The Dissertation Committee for Nicole Streuding Murry certifies that this is the approved version of the following dissertation:

THE IMPACT OF HEALTH LITERACY ON SELF-CARE ACTIVITIES AMONG UNDERSERVED PATIENTS WITH TYPE 2 DIABETES

Committee:

Miyong T. Kim, Supervisor

Patricia A. Carter

Kavita Radhakrishnan

Michael S. Mackert

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by

Nicole Streuding Murry

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Dedication

This dissertation is dedicated to underserved patients across the U.S. and healthcare systems working to improve their care.

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"Tell me and I forget, teach me and I may remember, involve me and I learn."

- *Benjamin Franklin*

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"I would rather walk with a friend in the dark, than alone in the light."

- *Helen Keller*

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"I sustain myself with the love of family."

- *Maya Angelou*

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The Impact of Health Literacy on Self-Care Activities among Underserved Patients with Type 2 Diabetes

Nicole Streuding Murry, Ph.D.

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Supervisor: Miyong T. Kim

To maintain good health, patients with Type 2 diabetes (T2DM) must perform self-care activities (SCA), many of which require health literacy – the ability to obtain, find, and use healthcare information to make decisions about health. In this dissertation, using the information-motivation-behavioral skills theoretical framework, I assess and examine health literacy in relation to SCA among underserved people with T2DM.

This descriptive correlational study is a secondary analysis of data from a larger study of participants from six federally qualified health centers in an urban county in South Central Texas. The sample comprised 388 patients with T2DM (261 English-speaking, 127 Spanish-speaking; 53$\pm$10.33 years old), with the majority reporting an annual income of less than $10,000. Functional health literacy was measured with the Newest Vital Sign screening tool; diabetes-specific oral health literacy, with the DM-REALM – a modification of the original REALM instrument. Only 18.3% of participants exhibited adequate functional health literacy; 10.4%, adequate oral health literacy.

In bivariate analysis, functional health literacy was related to age, gender, language, acculturation, income, education, and marital status. Oral health literacy was related to gender, employment status, and type of insurance. Significant predictors of functional health literacy included gender, education, and type of insurance. Significant

predictors of oral health literacy included gender, employment status, and years with T2DM. In bivariate analysis, diabetes self-efficacy and health information-seeking behaviors were related to diabetes SCA. In hierarchical multiple regression, functional health literacy, health information-seeking behaviors, and diabetes self-efficacy were significant predictors of diabetes SCA. Although health literacy did not exhibit a significant direct effect on diabetes SCA, health information-seeking behaviors mediated the relationship between oral health literacy and diabetes SCA.

These findings add to previous findings showing the high prevalence of limited health literacy among underserved people and the negative influence of limited health literacy on SCA among people with T2DM. Further studies of the impact of limited health literacy on diabetes SCA in diverse, underserved populations of people with T2DM are warranted. Future health literacy interventions should incorporate individual- and systems-level approaches in addressing promotion of diabetes SCA.

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Chapter One: Introduction

Health literacy has been described as the "knowledge, motivation, and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course" (Sørensen et al., 2013, p. 3). According to the results of the highly cited 2003 National Assessment of Adult Literacy, approximately one third of all Americans have limited health literacy (Kutner, Greenberg, Jin, & Paulsen, 2006). These limitations have been linked to a host of negative health consequences, including improper medication administration, overuse of emergency medical care services, misinterpretation of post-hospital discharge instructions, and poor chronic disease self-management (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011).

Diabetes mellitus (hereafter *diabetes*) is among the most prevalent chronic diseases in the United States. It is estimated that 30 million Americans (9.4% of the U.S. population) are currently living with diabetes (Centers for Disease Control and Prevention [CDC], 2017). In addition to known traditional risk factors such as a lack of physical activity and a family history of diabetes, emerging research has demonstrated that "living in poverty" is a major risk factor for developing the disease (Dinca-Panaitescu et al., 2012; Gaskin et al., 2014). Moreover, underserved patients with diabetes are more likely to suffer from serious complications such as cardiovascular disease, blindness, and limb amputations (Murea, Ma & Freedman, 2012; Stevens et al., 2014; Walker, Gebregziabher, Martin-Harris, & Egede, 2014; Walker, Strom Williams,

& Egede, 2016). Several critical social determinants of health associated with being underserved, such as chronic stress, limited access to healthy foods, and lack of access to quality healthcare services, have been identified contributing to high prevalence and poor management of diabetes.

Health literacy (HL) has been identified as a potential facilitator of optimal self-management of chronic diseases, including diabetes (Mackey, Doody, Werner, & Fullen, 2016), and self-management is the foundation of optimal health among patients with Type 2 diabetes (T2DM; Nagelkerk, Reick, & Meengs, 2006). T2DM self-management is complex; it includes self-care activities (SCA) such as adherence to specific instructions regarding diet, exercise, blood-glucose monitoring, foot care, and medication administration (Glasgow et al., 1989; Ruggiero et al., 1997). Yet although a growing number of researchers argue that HL plays a critical role in SCA among people with T2DM (Brega et al., 2012; Cavanaugh et al., 2008; Mbaezue et al., 2010; McCleary-Jones, 2011), that relationship is not always consistently recognized. Several studies have failed to capture the direct effect of HL on diabetes SCA (Al Sayah, Majumdar, & Johnson, 2015; Bowen et al., 2013; Kim, Love, Quistberg, & Shea, 2004; Mancuso, 2010; Osborn, Cavanaugh, Wallston, White & Rothman, 2009; Sarkar, Fisher, & Schillinger, 2006; Schillinger et al., 2002; Shigaki et al., 2010; White, Osborn, Gebretsadik, Kripalani, & Rothman, 2011).

In addition, the majority of research on HL and T2DM SCA is not guided by a theoretical framework. As a result, specific mediators of HL have not been identified, nor have plausible pathways that might explain how HL may influence SCA and/or outcome

variables. Also, most authors have used a global HL measurement rather than a diabetes-specific HL measurement. Finally, few studies have examined the role of HL in priority populations that traditionally suffer from low HL, such as people living in states along the US–Mexico border, non-English speakers, and those at the highest risk of poverty.

These scientific gaps highlight reasons for the research in this dissertation as well as needed directions of future research. The current state of the science shows the following methodological gaps: (1) the lack of a theoretical framework that specifies the pathway of HL's influence on diabetes SCA for respective target populations, (2) a limited sensitivity and specificity of HL measures along with cultural relevancy for respective target populations, and (3) a lack of empirical research that explicates differential roles of HL in populations struggling with important social determinants of health such as poverty and language barriers.

PURPOSE OF THE STUDY

The purposes of this study are (1) to describe the health literacy levels of underserved patients with T2DM, (2) to determine the strength and direction of the relationship between health literacy and T2DM SCA, and (3) to examine pathways among theoretically selected variables, including information (health literacy and diabetes-related knowledge), motivation (health information-seeking behaviors), behavioral skills (diabetes self-efficacy) and health behaviors (diabetes SCA).

BACKGROUND AND SIGNIFICANCE

This research has strong potential to contribute to the field of HL and self-management science, as well as health disparity research. Despite a growing number of

studies on areas of health disparities, studies that explicate the complex interplay between limited HL, low socio-economic status, chronic disease, and their relationships to health status of underserved populations are scarce. In particular, little is known about people who reside in low-income communities with a high proportion of first generation immigrant groups, because people with limited resources and/or limited English skills are often excluded from participating in such research (Timmins, 2002). This research therefore addresses critical knowledge gaps in the field of chronic disease management for people with limited resources by critically examining relationships among levels of information, motivation, behavioral skills and behaviors among underserved people with T2DM.

Review of the recent literature shows a lack of homogeneity among sample attributes, study design, choices of theoretical frameworks, and health literacy instrumentation, which makes it difficult to generalize research findings. Several methodological considerations should be made in order to reconcile the seemingly valid theoretical propositions regarding the positive effect of HL on diabetes SCA.

In summary, this study is significant because it (1) focuses on underserved populations; (2) contributes to the understanding of the influence of health literacy on SCA among underserved people with T2DM; and (3) uses two diabetes-specific instruments (the Newest Vital Sign [NVS] and the Rapid Estimate of Adult Literacy in Medicine for diabetes [DM-REALM]) to measure health literacy.

Focus on underserved populations. Underserved populations, including ethnic minorities and the poor, are disproportionately affected by limited health literacy (Ad

Hoc Committee on Health Literacy for the Council on Scientific Affairs, 1999; Easton, Entwistle, & Williams, 2010). Although T2DM self-care and HL literature reports the inclusion of a diversity of people with regard to race, education level, and income in healthcare systems across North America, some important gaps exist. Most HL and diabetes SCA studies focus on black participants with T2DM (Al Sayah, Majumdar, Egede, & Johnson, 2015; Heinrich, 2012; Kim et al., 2004; Mancuso, 2010; Mbaezue et al., 2010; McCleary-Jones, 2011; Miser, Jeppesen, & Wallace, 2013; Piatt, Valerio, Nwankwo, Lucas, & Funnell, 2014; Rothman et al., 2004; Rothman et al., 2005), and few have focused primarily on Latinos (Kenya et al., 2015; Sarkar et al., 2006; Seligman et al., 2005; Smith-Miller, Berry, DeWalt & Miller, 2016; White et al., 2011). Latino/as now constitute nearly 18% of the U.S. population (U.S. Census Bureau, 2018), with the highest density in the south and southwest. The number of Latino/as living in the U.S. is expected to double in the next 50 years (U.S. Census Bureau, 2018). Geographic diversity among studies is partly to blame for the lack of racial equity among participants. The majority of studies have taken place in the southeastern U.S., and Mexico-bordering states have been, for the most part, excluded from this research. In addition, non-English speaking participants have been largely excluded. The reason for this exclusion is often unclear, but the lack of resources for translating services or the unavailability of bilingual data collectors is often cited (Medrano et al., 2010). This trend is not unique; non-English speaking participants are rarely included in behavioral research (Timmins, 2002). Language barriers are an important consideration in access and adequate utilization of the health care system.

Lower socioeconomic status has been associated with poor glycemic control (Houle et al., 2015). Poor glycemic control is the primary contributor to major complications including nephropathy, retinopathy, and cardiovascular disease (American Diabetes Association, 2016). Poverty also plays an important role in SCA; lower socioeconomic status has been associated with poor diabetes SCA (Goldman & Smith, 2002; Levine, Allison, & Cherrington, 2009).

Very few attempts to establish the relationship between health literacy and SCA have successfully recruited representative numbers of ethnic minority, non-English speaking people with T2DM in a Mexico-bordering state.

Health literacy and self-care activities among people with T2DM. Earlier studies often sought to describe the effect of health literacy on more distal diabetes outcomes, such as glycemic control (HbA1c). Among a selection of such studies, very few found a statistically significant correlation between the two (Cavanaugh et al., 2008; Osborn et al., 2009; Piatt et al., 2014; Schillinger et al., 2002), and most failed to identify a relationship between HL and HbA1c (Al Sayah et al., 2015; Al Sayah et al., 2015; Brega et al., 2012; Kenya et al., 2015; Kim et al., 2004; Mancuso, 2010; Morris, MacLean & Littenberg, 2006; Rothman et al., 2004; White et al., 2011). Although HbA1C is an important measure of glycemic control, it is not a complete representation of a person's participation in diabetes related SCA.

More recently, there has been a growing trend to focus on more proximal health outcomes, such as diabetes SCA. Among patients with T2DM, these activities include adherence to regimens pertaining to diet, exercise, blood-glucose monitoring, foot care,

and medication administration (Glasgow, Barrera, McKay & Boles, 1999; Ruggiero et al., 1997). Various instruments have been used to measure SCA among people with T2DM. Among 14 studies that sought to measure the relationship between HL and diabetes SCA, 10 used the Summary of Diabetes Self-Care Activities (SDSCA; Al Sayah et al., 2015; Cavanaugh et al., 2008; Cavanaugh et al., 2009; Graumlich et al., 2016; Kim et al., 2004; Mancuso, 2010; McCleary-Jones, 2011; Sarkar et al., 2006; Shigaki et al., 2010; White et al., 2011). The SDSCA is an 11-item self-report assessment that measures various diabetes SCA including blood glucose testing, diet, exercise, foot care, and smoking behaviors over the past 7 days (Toobert & Glasgow, 1994). Other studies have used a variety of methods to capture SCA. Blood glucose monitoring, dietary intake, and physical activity are among the most popular singular SCA studied. Self-monitoring of blood glucose (SMBG) was extracted from data collected with the Diabetes Care Profile in one study (Mbaezue et al., 2010). Dietary intake was measured in three ways: with the Block-FFQ (Bowen et al., 2013), through a question related to fruit and vegetable intake from the Behavioral Risk Factor Surveillance System (BRFSS) survey (Kenya et al., 2015), and through self-report in another (Brega et al., 2012). This lack of homogeneity among methods to measure diabetes SCA makes it difficult to synthesize research findings.

Only four of the 14 studies were able to identify a statistically significant correlation between diabetes SCA and HL. No relationships were identified between HL and collective measures of diabetes SCA (such as the summative score of the SDSCA), but three individual diabetes SCA that exhibited a relationship with HL included self-

monitoring of blood glucose, foot self-care, and dietary practices. Two studies identified a statistically significant correlation between HL and self-monitoring of blood glucose (Brega et al., 2012; Mbaezue et al., 2010). McCleary Jones (2011) identified a relationship between HL and foot self-care, and Brega (2012) identified a relationship between HL and food consumption. In this selection of literature, there seems to be little evidence that health literacy is related to diabetes SCA.

Health literacy instrumentation in diabetes self-care activity research. In the existing literature, there is a troubling lack of homogeneity among HL instruments used in T2DM self-care research. Although the role of HL in chronic disease management is well documented, few HL intervention studies have been reported. A major barrier to designing and implementing such interventions may be a lack of sensitive HL tools; the lack of homogeneity among HL instruments is discussed in the literature (Sørensen et al., 2013), but little effort has been made to establish a "gold standard" for specific populations of people.

The literature review for this dissertation yielded 25 studies regarding SCA and HL among people with T2DM, which are here analyzed for HL instrumentation choice and use. Among these studies, seven different instruments were used to measure health literacy or numeracy. The most common instruments for health literacy were the REALM (Bowen et al., 2013; Cavanaugh et al., 2008; Cavanaugh et al., 2009; Graumlich et al., 2016; McCleary-Jones, 2011; Osborn et al., 2009; Rothman et al., 2004; Rothman et al., 2005) and the Short Test of Functional Health Literacy in Adults (S-TOFHLA; Kim et al., 2004; Mbaezue et al., 2010; Miser et al., 2013; Morris et al., 2006; Sarkar et al., 2006;

Schillinger et al., 2002; Seligman et al., 2005; White et al., 2011). Typically citing and testing clinical utility, others used the NVS to measure health literacy (Heinrich, 2012; Miser et al., 2013; Piatt et al., 2014; Shigaki et al., 2010). Three utilized the Chew 3-Item HL Scale (Al Sayah et al., 2015; Al Sayah et al., 2013; Brega et al., 2012), and the Short Assessment of Health Literacy for Spanish-speaking Adults (SAHLSA) was used in two studies targeting Spanish-speaking participants (Kenya et al., 2015; Smith-Miller et al., 2016). Some studies incorporated the Diabetes Numeracy Test (DNT-15) as a measure of numeracy skills (Bowen et al., 2013; Cavanaugh et al., 2008; Cavanaugh et al., 2009; Osborn et al., 2009; White et al., 2011), and three incorporated the use of the math portion of the Wide Range Achievement Test, 3rd or 4th edition (Cavanaugh et al., 2008; Osborn et al., 2009; White et al., 2011).

Overall, the three most common measures of HL in patients with T2DM were the REALM, S-TOFHLA, and NVS. These three instruments all claim to measure the same construct (HL), but they differ greatly in administration method, time needed for administration, difficulty, scoring, and reporting of results. This lack of homogeneity makes it difficult to synthesize study findings for HL. The REALM and the Test of Functional Health Literacy in Adults (TOFHLA) assess broad and global levels of HL rather than disease- or context-specific health literacy, whereas the NVS focuses more on the participant's ability to interpret a nutrition label (an essential management skill for diabetes management). In designing the original research project, two instruments were chosen to assess health literacy more holistically. The NVS, a functional HL measurement designed specifically for DM patients (Weiss et al., 2005), was selected to

address document and print literacy, as well as numeracy. The NVS presents patients with a nutrition label from a container of ice cream and the facilitator then asks them six questions about the content on the label, which requires both literacy and numeracy skills. Diet management, an essential T2DM self-care activity, relies heavily on the ability to read and interpret a nutrition label. A modified version of the REALM – the diabetes-specific DM-REALM – was used to assess print and oral literacy.

Findings from this study regarding the psychometric properties of the NVS and the DM-REALM should help inform other clinical researchers and practitioners when they evaluate diabetes-specific HL in linguistic minority patients.

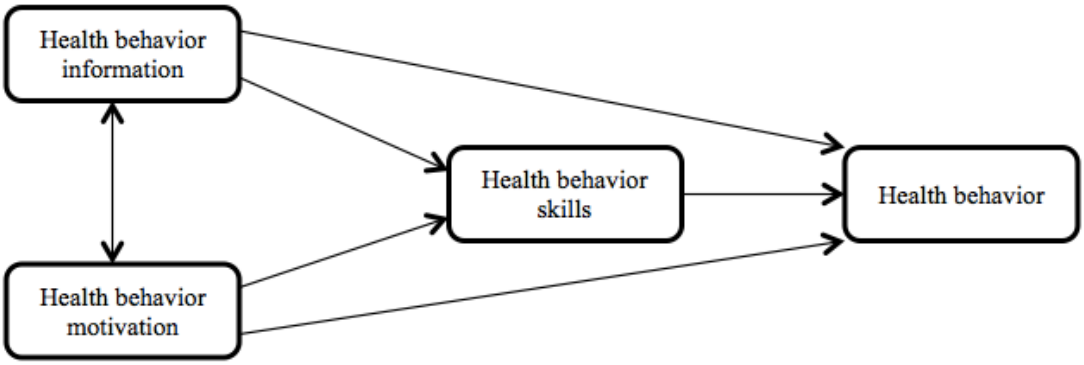
CONCEPTUAL FRAMEWORK

Few authors of T2DM SCA and HL studies have explicitly identified a theoretical basis for their studies' designs. Among the 25 studies reviewed for this study, only four identified a theoretical framework. Of those, two used the same framework – social cognitive theory. The other two identified existing health literacy frameworks – the IOM HL and Paasche-Orlow's 2007 HL. One identified the theory of self-determination; one identified process-knowledge theory; and one proposed a new theory linking self-efficacy and HL (Mancuso, 2010). This lack of consensus regarding theoretical frameworks and definitions of key variables and pathways among relevant variables often results in inconsistent findings and ultimately in an inability to find meaningful mediators that influence SCA in T2DM populations. It is often argued that theoretical frameworks can be too narrow, too intricate, and not easily generalizable. Without a common link among theoretical frameworks, however, any synthesis of study findings is very difficult. For

this reason, a more general yet succinct theory was chosen to guide this study.

The information-motivation-behavioral skills (IMB) theoretical framework (Fisher & Fisher, 1992) guides this exploration of factors related to SCA among people with T2DM (Figure 1). The IMB model was initially proposed to explain risk-taking behaviors among those with AIDS in diverse populations. In its original form, the model proposed that a reduction in AIDS-risk behaviors was directly related to the information that people received about these behaviors, to their motivation to act on that information and reduce their risk of AIDS, and to their ability to perform relevant AIDS-risk reduction behavioral skills. Over the last 30 years, researchers have applied this framework beyond the AIDS population and have generalized the model for use in studies among people with various chronic diseases. In recent years, the model has been used as a framework in several studies of SCA in people with T2DM (Gao, Wang, Zhu, & Yu, 2013; Mayberry & Osborn, 2014; Meunier et al., 2016; Osborn & Egede, 2010; Osborn, Rivet Amico, Fisher, Egede, & Fisher, 2010). The model focuses comprehensively on the information, motivation, and behavioral skills that are necessary to perform health-related behaviors. It asserts that a person's likelihood to initiate health-promoting behaviors (which result in positive health outcomes) depends on how well informed and motivated the person may be (Fisher, Fisher, & Harman, 2003).

Figure 1. *Information-Motivation-Behavioral Skills Theoretical Model of Health Behavior*



The Information-Motivation-Behavioral Skills Model of health behavior. From J. D. Fisher and W. A. Fisher (1992). Changing AIDS risk behavior. *Psychological Bulletin*, 111, 455-74.

The model explains a causal pathway among constructs. The theory asserts that if people are provided with appropriate information, are motivated to act, and have the appropriate behavioral skills necessary for effective action, they will be able to perform health behaviors that result in positive health outcomes (Fisher & Fisher, 1992). The theory also acknowledges that factors such as socioeconomic status and social support can moderate the relationships among constructs in the model. The framework is both comprehensive and parsimonious. The IMB model is regarded as a highly generalizable framework for understanding and fostering health behaviors across many health domains (Fisher et al., 2003). A review of the literature (Fisher & Fisher, 2000) has shown that assumptions of the IMB model are empirically supported by several studies using multivariate correlation. Beyond the HIV literature, IMB studies have spanned a variety of domains, including smoking cessation, cardiovascular health, breast health, nutrition, and physical activity.

Information. The IMB theory asserts that information that is actionable and relevant to a health behavior is critical to performing a particular health behavior (Fisher & Fisher, 1992; 2000). *Information* generally refers to health risk prevention, health promotion, or behavioral visual or audible information.

Motivation. Another critical determinant of health-related behaviors asserted by this framework is motivation. Two types of motivation influence a person's performance of a health-related behavior: personal and social (Fisher & Fisher, 1992). Personal motivation includes attitudes toward personal performance of the behavior, whereas social motivation often includes social support that a person receives to perform a certain health behavior.

Information and motivation are regarded as potentially independent constructs; better-informed people do not always have the motivation to perform health-promoting behaviors, and conversely, those who are highly motivated are not necessarily well informed (Fisher & Fisher, 1992).

Behavioral Skills. The IMB model proposes that behavioral skills are related to a person's objective abilities to enact health promotion behaviors. The model also asserts that when behavioral skills are not overly complex, motivation and information may have a direct effect on health promotion behavior (Fisher & Fisher, 2000).

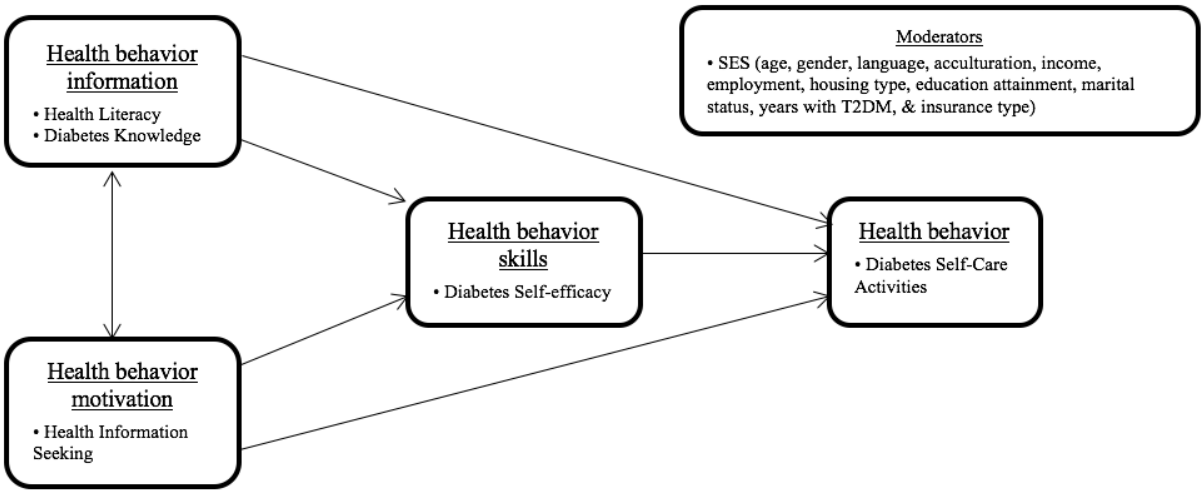
The model stipulates that health information and motivation work in partnership, primarily through behavioral skills, to influence health promotion behavior (Fisher & Fisher, 1992). Studies have consistently shown that information alone is not enough to change health behavior (Knight, Dornan, & Bundy, 2006; Norris, Engelgau, & Narayan,

2001). However, interventions that include a combination of information, motivation, and behavioral skills content are far more effective at influencing behavior change (Fisher & Fisher, 2000).

Health Behavior. As the highly generalizable model suggests, health behavior can be any specific health promotion or illness prevention activity.

For the proposed study, Fisher and Fisher's model has been revised to describe SCA among people with T2DM (Figure 2). Because the original theoretical model was designed for intervention research (Fisher & Fisher, 1992), it required minor adaptation for this descriptive study. In previous intervention research guided by this model, *health behavior information* is often the intervention's focus and it refers to the provision of appropriate and actionable health information related to the health problem of interest. However, for this study, it refers to personal attributes that the person may possess that are related to information acquisition – health literacy and diabetes knowledge.

Figure 2. *Proposed modification of the IMB Theoretical Framework*



Health literacy is integral to how people seek, perceive, and use health information (Berkman, Davis, & McCormack, 2010; Nutbeam, 2000). To further illustrate health behavior information, this model proposes that measuring the amount of diabetes knowledge an individual possesses can elucidate the construct more fully. Diabetes knowledge has been closely related to health literacy (Al Sayah et al., 2015; Gazmarian, Williams, Peel & Baker, 2003; Kim et al., 2004; Mancuso, 2010; Rothman et al., 2005). Together, an individual's level of health literacy and diabetes knowledge may better show how health behavior information acquisition impacts health behavior skills and, ultimately, health behavior outcomes in this proposed model. Health information-seeking behavior is an important measure of motivation. Diabetes self-efficacy is an important element of one's behavioral skills. Without self-efficacy, patients' activation to perform essential behavioral skills would be difficult. As in Bandura's (1986) social

cognitive theory, self-efficacy is a person's confidence that he or she can do something and can successfully act to promote a change. Inconsistencies regarding the information, motivation, and behavioral skills necessary for successful execution of SCA among people with T2DM call for more rigorous, theory-guided research. The IMB model has the potential to appropriately identify a plausible pathway of HL's potential influence on SCA and/or outcome variables. For these reasons, the IMB model was modified and used to frame this dissertation study.

RESEARCH QUESTIONS

Based on the subsequent review of the literature and this study's theoretical framework, the research questions are as follows:

1. What are the magnitude and direction of the relationships among personal characteristics (age, gender, language, acculturation, income, employment, housing type, education attainment, marital status, years with T2DM, and insurance type) and health literacy among underserved patients with T2DM?
2. What are the magnitude and direction of the relationships among health literacy, diabetes knowledge, health information-seeking behaviors, diabetes self-efficacy, and diabetes SCA among underserved patients with T2DM?
3. Are there differences among diabetes knowledge, health information-seeking behaviors, diabetes self-efficacy, or diabetes SCA between those with limited health literacy and those with adequate health literacy?
4. What are the significant predictors of the level of health literacy among underserved patients with T2DM?
5. What are the significant predictors of diabetes SCA among underserved patients with T2DM?
6. Do health information-seeking behaviors and/or diabetes self-efficacy mediate the effects of health literacy on diabetes SCA among underserved patients with T2DM?

DEFINITIONS OF CONCEPTS

Information

Health Literacy

Conceptual definition: There is no single definition of health literacy. The definition most commonly cited was proposed by Ratzan and Parker (2000): "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make health decisions" (p. 7). For the present study, health literacy may be described more broadly, as "the knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course" (Sørensen et al., 2013, p. 3). This definition also incorporates each of the elements of the IMB theoretical model.

Operational definition: The summed score of the NVS was used to measure functional health literacy, and the DM-REALM was used to measure diabetes-specific oral health literacy.

Diabetes Knowledge

Conceptual definition: Knowledge is defined as the facts, information, and skills acquired by a person through experience or education; the theoretical or practical understanding of a subject (Merriam-Webster, 2017).

Operational definition: The summed score of the Michigan Diabetes Knowledge Test (MDKT) was used to measure diabetes knowledge.

Motivation

Health Information-Seeking Behaviors

Conceptual definitions: Individual information-seeking behaviors are described by Johnson and Meischke (1993) as "the purposive acquisition of information from selected information carriers" (p. 344). Health information-seeking is "the active engagement in the search for specific health information that is prompted by a relevant event, such as the development of symptoms, or given a medical diagnosis (Niederdeppe et al., 2007).

Operational definition: Health information-seeking behaviors were measured by a 6-item subscale of Porter Novelli's HealthStyles 1999 and 2003 consumer opinion surveys – referred to as the Health Information-Seeking Behaviors Scale (HISB).

Behavioral Skills

Diabetes Self-Efficacy

Conceptual definition: Self-efficacy is "the belief in one's capabilities to organize and execute the courses of action required to manage prospective situations" (Bandura, 1995, p. 2). Judgments of self-efficacy are not simply non-specific feelings of control or success; they are explicit to a particular behavior or setting (Cervone & Peake, 1986). Diabetes self-efficacy is related to an individual's belief that he or she can successfully manage the disease.

Operational definition: Diabetes self-efficacy was measured with the Stanford Self-Efficacy for Managing Diabetes Scale.

Health Behavior

Diabetes Self-Care Activities

Conceptual definition: With the ultimate goal of maintaining glucose levels in a target range, the combination of diabetes SCA includes following a healthy eating plan, regularly exercising, self-testing of blood glucose levels, and regularly taking diabetes medication, if prescribed (Glasgow et al., 1999; Ruggiero et al., 1997).

Operational definition: Diabetes SCA were measured using the summed score of the Summary of Diabetes Self-Care Activities Scale (including diet, exercise, blood glucose self-testing, and foot care).

LIMITATIONS

The limitations of this study include the following:

1. The findings may reflect participant bias, because those more likely to participate might be more eager to seek out health information, have less concern about their ability to read, or be financially motivated by the incentive provided.
2. The findings may reflect a response or social desirability bias, because data collectors were students from a highly regarded local university.
3. The cross-sectional descriptive design of the study cannot determine causality.
4. Generalizability of the findings is limited because of the non-randomized convenience sampling technique.

SUMMARY

This chapter has presented the study's purpose, background, significance, theoretical framework, and research questions, highlighting the need to study the strength and direction of relationships between information, motivation, and health behaviors among underserved patients with T2DM. This descriptive, cross-sectional study of the information, motivation, behavioral skills, and behaviors among underserved patients with T2DM is intended to (1) describe the levels of health literacy among underserved people with T2DM; (2) present the use of a more generalizable theoretical framework to specify pathways of the influence of health literacy on diabetes SCA for this target population; and (3) determine the strength and direction of relationships among these theoretically bound variables. An adapted version of the information-motivation-behavioral skills theoretical model (Fisher & Fisher, 1992) provides the study's conceptual framework. The results will help inform future research regarding health literacy and T2DM SCA among underserved people.

Chapter Two: Review of the Literature

Diabetes requires a complex degree of self-management skills (American Diabetes Association, 2016; Goodall & Halford, 1991; Nagelkerk et al., 2006). In addition to more frequent interaction with healthcare practitioners, people with diabetes engage in a variety of SCA that include dietary modification, physical exercise, frequent blood glucose monitoring, recognition of signs & symptoms of hypo/hyperglycemia, daily foot care, adherence to medication and for some, insulin administration (Glasgow et al., 1989; Ruggiero et al., 1997). Self-management was first described as a patient's active participation in their healthcare needs. However, over time, this definition has evolved to more broadly include the daily activities patients participate in to manage their chronic illness (Lorig & Holman, 2003). Although the clinical characteristics differ, chronic diseases such as cancer, cardiovascular disease and diabetes all share similar and complex self-care activity regimes that include dietary and physical activity recommendations, medication adherence, symptom awareness and frequent interactions with the healthcare system (Wagner et al., 2001). Health literacy plays an important role in many of these activities (Al Sayah, Majumdar, Williams, Robertson, & Johnson, 2013).

It has been estimated that nearly 90 million adults in the United States do not have the health literacy skills to adequately engage the healthcare system (Kindig, Panzer & Nielsen-Bohlman, 2004). Low health literacy has been linked to many negative healthcare activities including the misinterpretation of medication labels, misunderstanding discharge instructions, and medical appointment adherence (Berkman

et al., 2011). Additionally, limited health literacy has been linked to poverty (Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, 1999; Easton et al., 2010). Limited health literacy is not only dangerous, but is costly. It was estimated that the annual costs of healthcare attributed to limited health literacy could be between $106 billion and $238 billion (Vernon, Trujillo, Rosenbaum, & DeBuono, 2007). It is for these reasons that improving health literacy has been identified as an objective for Healthy People 2020 (U. S. Department of Health and Human Services, 2017).

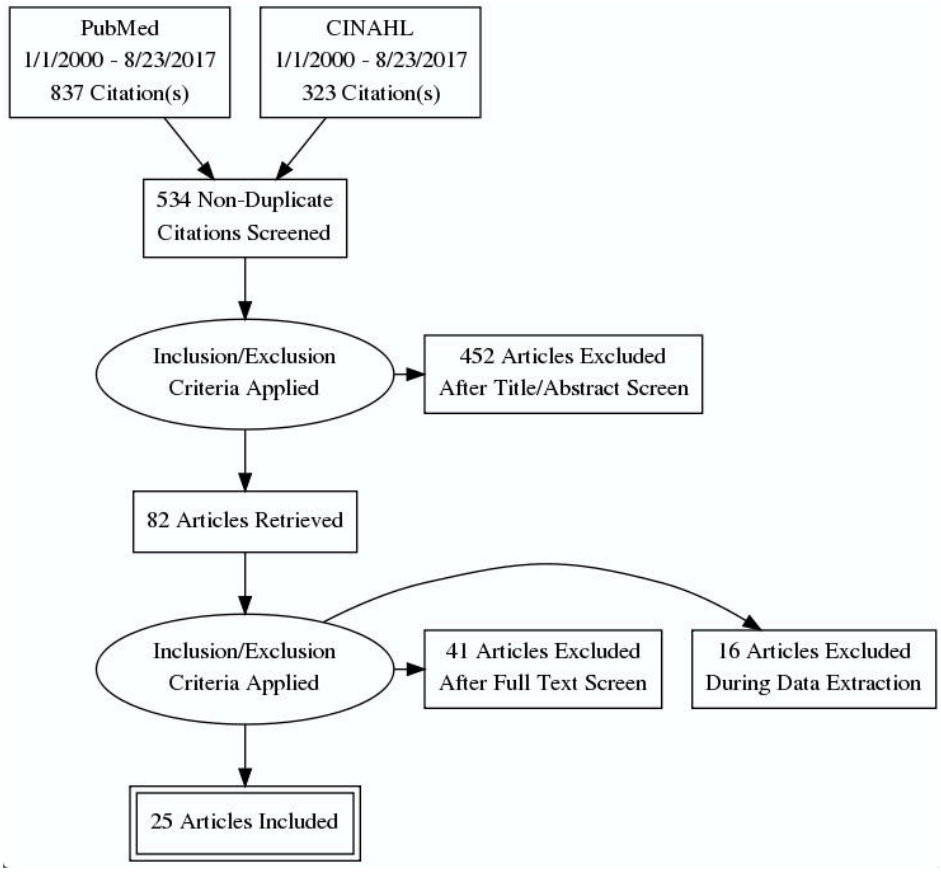
This literature review aims to report on evidence found in the literature linking health literacy to diabetes SCA. The findings of this literature review are presented in Table 1. Health literacy, the primary focus of this study, is a relatively new concept, emerging more frequently in the literature around the year 2000. For that reason, studies included in this literature review were limited to those conducted between 2000 and 2017. After careful consideration and in light of the differences among healthcare systems in countries beyond the US and Canada, study sites were limited to North America.

For this review of the literature, 2 online databases were searched including: CINAHL, and PubMed. To locate relevant studies, the following search terms were used in a variety of combinations: health literacy, numeracy, diabetes, diabetic, Type 2 Diabetes (T2D), self-management, self-care, TOFHLA, S-TOFHLA, Newest Vital Sign, Short Assessment of Health Literacy, REALM, and WRAT. In addition, the bibliographies of each included study were reviewed to ensure all relevant studies were identified.

Studies that were considered for inclusion had to be quantitative in design, take place in North America (US or Canada) and written in English. The sample included adult patients diagnosed with Type 2 Diabetes. The studies had to include some measurement of health literacy or numeracy and published in the last 17 years. After careful consideration, studies were excluded if the sample of patients included those outside of North America as care guidelines of patients with Type 2 Diabetes may vary outside of this geographic area.

After eliminating duplicate results from CINAHL and PubMed, 534 titles were reviewed for inclusion. Of those, 440 studies were eliminated by title alone. After that elimination, 112 abstracts were then read for inclusionary criteria. Literature reviews, commentaries, and non-peer reviewed studies were excluded. After applying exclusionary criteria for the abstract review, 30 were eliminated, leaving 82 for full text review. Forty-one articles were excluded after full-text screening and an additional 16 were excluded during data extraction (Figure 3). Using a thorough review process and strict adherence to inclusionary criteria, 25 studies were ultimately included in this review of the literature.

Figure 3. *Literature search strategy*



The studies included in this literature review used either a cross-sectional descriptive design or a randomized controlled clinical trial (RCT) design. However, among the four RCT studies, the data extracted for the purposes of this literature review were collected at just one point in time and health literacy was used as a baseline measurement (Al Sayah et al., 2015; Cavanaugh et al., 2009; Graumlich et al., 2016; Seligman et al., 2005). When HbA1C data was used for analysis, it was usually the last level drawn within the past year and was obtained by medical record review.

At the heart of HL is the ability to read, understand (oral/print literacy), and take appropriate action for his or her health (functional HL). Literacy remains a challenge for many Americans, with only 32% of Americans in a nationally representative sample exhibiting proficient literacy skills (National Center for Education Statistics, 2005). To overcome the high likelihood of encountering participants that would be unable to read, surveys were often administered in person by a research assistant (RA) who could quickly assess to what extent the participant may need assistance to complete the questionnaire (Bowen et al., 2013; Cavanaugh et al., 2008; Mancuso, 2010; Mbaezue et al., 2010; Miser et al., 2013; Morris et al., 2006; Osborn et al., 2009; Rothman et al., 2005; Sarkar et al., 2006; Schillinger et al., 2002; Shigaki et al., 2010; Smith-Miller, et al., 2016; White et al., 2011). However, for the other half of studies included in this review, the mode of data collection and participant support was unclear due to insufficient description. It is possible that some participants who could not read or understand questions but still used a self-administration method might not be able to provide authentic responses.

The sample sizes of each of the studies ranged from 30 to 2594 participants, with an average of 341 participants. This review summarizes health literacy among patients with Type 2 Diabetes (T2DM) among a total of 8,536 adults. All were adult participants. Most participants were recruited from either primary care or diabetes specialty clinics (Al Sayah et al., 2015; Bowen et al., 2013; Cavanaugh et al., 2008; Graumlich et al., 2016; Kenya et al., 2015; Mancuso, 2010; Mbaezue et al., 2010; McCleary-Jones, 2011; Osborn et al., 2009; Rothman et al., 2004; Rothman et al., 2005; Sarkar et al., 2006; Schillinger et

al., 2002; Seligman et al., 2005; White et al., 2011; White, Wolff, Canvanaugh & Rothman, 2010), but participants were also recruited from community spaces (Smith-Miller et al., 2016) and from diabetes education classes (Kim et al., 2004). Eleven of the 21 studies recruited participants in the southeastern United States, either from Tennessee, North Carolina, South Carolina or Georgia. Five studies took place in the Midwestern United States (Graumlich et al., 2016; Mancuso, 2010; McCleary-Jones, 2011; Miser et al., 2013; Piatt et al., 2014), two studies took place in San Francisco, CA (Sarkar et al., 2006; Schillinger et al., 2002), two in the northeastern U.S. (Kim et al., 2004; Morris et al., 2006), one in Southern Florida (Kenya et al., 2015), one was from a national database (Brega et al., 2012) and two did not specify location (Seligman et al., 2005; Shigaki et al., 2010). Only one of the studies collected data from participants outside of the U.S. – in Canada (Al Sayah et al., 2015). Most of the studies took place in either the southeastern or midwestern United States and while the populations included in these samples were relatively diverse, the sample falls short of the true diversity of ethnicities found in North America; particularly the diversity found along the US – Mexico border.

All of the studies included participants diagnosed with Type 2 Diabetes, however ten also included patients diagnosed with Type 1 Diabetes (Cavanaugh et al., 2008; Cavanaugh et al., 2009; Kim et al., 2004; Mancuso, 2010; Mbaezue et al., 2010; Miser et al., 2013; Morris et al., 2006; Osborn et al., 2009; Piatt et al., 2014; White et al., 2011). Although it was not always specified, T1DM typically comprised less than 5% of the sample, but did amount to as much as 15% in one study (Osborn et al., 2009). There are important differences among SCA for patients with T1DM and those with T2DM

(American Diabetes, 2011) such as variations in medication regimen (T1DM requires insulin administration & infrequently, oral medications while T2DM can require both), physical activity regimen, and healthy weight management (T1DM patients usually have a normal BMI while patients with T2DM often have an increased BMI). The differences should be considered when interpreting results about SCA from studies that include participants with both types of diabetes.

Less than optimal glucose control was often part of inclusion criteria, with either an HbA1c threshold $\geq$ 7% (Bowen et al., 2013; Cavanaugh et al., 2009) or $\geq$ 8% (Kenya et al., 2015; Rothman et al., 2004; Rothman et al., 2005). The average ages of participants in this collection of studies ranged from 47.8 – 66 years and the majority of participants were female (all 25 studies had 50% or more women and half of them included 60% or more women in the sample).

Overall, there was ethnic diversity among participants. Only 7 of the 25 studies included a majority of white participants (Al Sayah, et al., 2015; Bowen et al., 2013; Cavanaugh et al., 2008; Graumlich et al., 2016; Morris et al., 2006; Osborn et al., 2009; Shigaki et al., 2010) and most appeared to over sample ethnic minority participants. Ten studies included a majority of black participants (Al Sayah et al., 2015; Heinrich, 2012; Kim et al., 2004; Mancuso, 2010; Mbaezue et al., 2010; McCleary-Jones, 2011; Miser et al., 2013; Piatt et al., 2014; Rothman et al., 2004; Rothman et al., 2005), while 5 studies focused primarily on Latinos (Kenya et al., 2015; Sarkar et al., 2006; Seligman et al., 2005; Smith-Miller et al., 2016; White et al., 2011). Language barriers are an important consideration in access and adequate utilization of the health care system. With the

exception of the aforementioned five studies and one additional study (Schillinger et al., 2002), Spanish speakers were excluded from participation in the nineteen remaining studies.

Education attainment was usually reported as a percentage of participants with less than or equal to high school degree and was low for participants overall. Eight reported that greater than 60% of the sample attained no higher than a high school degree (Mancuso, 2010; Mbaezue et al., 2010; Morris et al., 2006; Rothman et al., 2004; Rothman et al., 2005; Schillinger et al., 2002), with one as high as 90% (White et al., 2011). Only eight of the 25 studies reported that less than half of their participants had less than a college education, but some studies did not report education level at all.

Similar to education level, reported income was low. Income was often reported as an annual income with $20,000 as the most common incremental category. For the purposes of this literature review, an annual income of $20,000 or less was a marker for poverty. Of the studies that included income as a sample attribute, 3 reported that more than 90% of their sample participants earned less than $20,000 annually (Sarkar et al., 2006; Schillinger et al., 2002), 7 reported a range of 50% - 90% of sample participants at or near the poverty level (Al Sayah et al., 2015; Kim et al., 2004; Mbaezue et al., 2010; Morris et al., 2006; Rothman et al., 2004; Rothman et al., 2005; White et al., 2011) and 9 reported a range of 20% - 50% of sample participants at or near the poverty level (Al Sayah et al., 2015; Bowen et al., 2013; Brega et al., 2012; Cavanaugh et al., 2008; Cavanaugh et al., 2009; Graumlich et al., 2016; Kenya et al., 2015; Osborn et al., 2009; Shigaki et al., 2010). Overall, the studies included in this literature review represent a fair

diversity of patients, in regards to race, education level and income in healthcare systems across North America. However, some important gaps are noted. Participants from Mexico-bordering states were for the most part, excluded from participation. In addition, non-English speakers were largely excluded. Finally, not separating T1DM and T2DM groups in a single study by design or analysis of data makes it difficult to interpret the pooled results of SCA studied as the type of diabetes makes contextually different SCA demands on an individual. In this study, these gaps were addressed as a diverse group of both English and Spanish-speaking participants from a Mexico-bordering state, diagnosed only with Type 2 Diabetes were recruited for participation.

HEALTH LITERACY AND DIABETES SELF-CARE ACTIVITIES

Among the 14 studies that sought to measure the relationship between HL and diabetes SCA, 10 measured them using the Summary of Diabetes Self Care Activities (SDSCA; Al Sayah et al., 2015; Cavanaugh et al., 2008; Cavanaugh et al., 2009; Graumlich et al., 2016; Kim et al., 2004; Mancuso, 2010; McCleary-Jones, 2011; Sarkar et al., 2006; Shigaki et al., 2010; White et al., 2011). The SDSCA is a 10-item self-report assessment that measures various diabetes self-care behaviors including blood glucose testing, diet, exercise, foot care and medication use over the past seven days (Toobert, Hampson, & Glasgow, 2000). Other studies used a variety of methods to capture SCA. Blood glucose monitoring, dietary intake & physical activity were among the most popular singular SCA studied. Self-monitoring of blood glucose (SMBG) was extracted from data collected with the Diabetes Care Profile in one study (Mbaezue et al., 2010). Dietary intake was measured in three ways; with the Block-FFQ in one study (Bowen et

al., 2013), through a question related to fruit and vegetable intake from the Behavioral Risk Factor Surveillance System (BRFSS) survey (Kenya et al., 2015) and through self-report in another (Brega et al., 2012).

Only four of the fourteen studies were able to identify a statistically significant correlation between diabetes SCA and HL. None of the studies included in this review identified a relationship between HL and the summed score of the SDSCA. However, when researchers used the sub-scales of the SDSCA, three SCA exhibited a relationship with HL; self-monitoring of blood glucose, foot self-care and dietary practices. More specifically, two studies identified a statistically significant correlation between HL and self-monitoring of blood glucose (Brega et al., 2012; Mbaezue et al., 2010). McCleary Jones (2011) identified a relationship between HL and foot self-care and Brega (2012) identified a relationship between HL and food consumption. Although seemingly, there is very little evidence in this selection of literature that HL is related to SCA.

The bulk of studies explicitly sought to describe the relationship between HL and more proximal outcomes, such as SCA. However, some sought to describe more distal outcomes, such as glycemic control (HbA1c) or a medical complication related to diabetes. Thirteen of the 25 studies sought to identify a relationship between HL and glycemic control, measured by HbA1c. Among those, four identified a statistically significant correlation between the two (Cavanaugh et al., 2008; Osborn et al., 2009; Piatt et al., 2014; Schillinger et al., 2002), but the remaining 9 failed to correlate HL with HbA1c (Al Sayah et al., 2015; Al Sayah et al., 2015; Brega et al., 2012; Kenya et al., 2015; Kim et al., 2004; Mancuso, 2010; Morris et al., 2006; Rothman et al., 2004; White

et al., 2011). Retinopathy and blood pressure were two diabetes complications reported in two different studies. Among those, only one identified a statistically significant relationship between a diabetes-related complication, retinopathy, and health literacy level (Schillinger et al., 2002), while the other failed to identify a relationship between systolic BP and HL (Al Sayah et al., 2015). Although these biological outcomes may be helpful markers of diabetes self-management, for this study, SCA was used as the primary outcome.

In summary, research regarding the relationship between health literacy and diabetes self care activities has yielded conflicting results. This discrepancy may be the result of the inconsistent methods researchers have used to measure diabetes self care activities among studies with similar aims. The majority of studies included the SDSCA evaluation tool to capture self care activities, but the remaining third chose either individual self care activities (such as daily monitoring of blood glucose, physical activity or fruit/vegetable intake). In this study, the SDSCA was used as it is the most comprehensive tool available to measure diabetes SCA and has been used extensively in diabetes research.

Table 1. Health Literacy and Self-Care Activities among Patients with Type 2 Diabetes

Author, Year Title	Sample/Setting/Demographics	Theoretical Frame Purpose	Study Design Data Collection	HL Measurement HL Results	Diabetes Behavior Inform/Motivation	Significant Findings (* p<.05, ** p<.01, *** p<.001)
Schillinger et al., 2002 Association of health literacy with diabetes outcomes. (Schillinger et al., 2002)	n = 408 patients with T2DM 2 Primary Care Clinics San Francisco, CA Age: 58.1 (mean) Sex, female: 58% Yrs with T2D: 9.5 (mean) HbA1c: 8.5% (mean) Ethnicity: Latino: 42% Black: 25% White: 15% Asian: 18% Ed ≤ HS: 69% Spanish: 36% Income: 93% < $20,000	None To identify the relationship between health literacy and health outcomes among patients with T2D in a public hospital system.	Cross-sectional observational Orally administered questionnaire and medical record review	**S-TOFHLA** Inadequate 38% Marginal 13% Adequate 49% Inad/Marg **51%** Mean score: 21	NR NR	**HL and Social Deter of Health:** Ed ≤ HS*** Uninsured or Medicare* Yrs with Diabetes*** Older age*** Nonwhite*** Spanish speaking*** **HL and SCA:** NR **HL and HbA1c/Complications:** HbA1c*** Retinopathy***
Rothman et al. (2004) The relationship between literacy and glycemic control in a diabetes disease-management program (Rothman et al., 2004)	n = 111 pts with T2DM, HbA1c ≥ 8% Primary Care Clinics North Carolina Age: 58 (mean) Sex, female: 60% Yrs with T2D: NR HbA1c: NR Ethnicity: Black: 75% Ed ≤ HS: 82% Spanish: Excluded Income: 62% on med assist	None To examine the role of literacy in glycemic control in a cohort of patients with T2D who were enrolled in a self-management program led by pharmacists.	Cross-sectional descriptive and MR review	**REALM** Low (<9th) 75% Adequate (≥9th) 25%	NR NR	**HL and Social Deter of Health:** African American*** Older age* Pts who required med assistance*** **HL and SCA:** NR **HL and HbA1c/Complications:** No sig association with HbA1c

Table 1. Health Literacy and Self-Care Activities among Patients with Type 2 Diabetes

Author, Year Title	Sample/Setting/Demographics	Theoretical Frame Purpose	Study Design Data Collection	HL Measurement HL Results	Diabetes Behavior Inform/Motivation	Significant Findings (* p<.05, ** p<.01, *** p<.001)
Kim et al. (2004) Association of health literacy with self-management behavior in patients with diabetes. (Kim, Love, Quistberg, & Shea, 2004)	n = 92 pts with T2DM (92%) or T1DM Diabetes education classes at the Hospital of UPenn Age: 60.27 (mean) Sex, female: 63.75% Yrs with T2D: 8.15 HbA1c: 8.4 Ethnicity: Black: 63.45% White: 32.32% Other: 3.4% Ed ≤ HS: 13.1 yrs, mean Spanish: Excluded Income: 51% < $20,000	None To examine the relationship between HL and SM behaviors in patients with diabetes. In addition, to determine whether diabetes education improves self-management behaviors in patients with limited compared with adequate HL.	Prospective observational Telephone interview (SDSCA & DKQ)	**S-TOFHLA** Inadequate 15% Marginal 8% Adequate 77% **Inad/Marg 23%**	Summary of Diabetes SCA Scale (SDSCA) Diabetes Knowledge Questionnaire	**HL and Social Deter of Health:** Less education* Lower annual income* More SR diab complications* Older age* **HL and SCA:** No sig association with SCA **HL and Inform/Motivation:** Better knowledge of diabetes* **HL and HbA1c/Complications:** No sig association with HbA1c
Rothman, et al. (2005) The spoken knowledge in low literacy in diabetes scale: a diabetes knowledge scale for vulnerable patients. (Rothman et al., 2005)	n = 217 pts with T2DM, HbA1c ≥ 8% Academic General Medicine Clinic in North Carolina Age: 55.1 (mean) Sex, female: 56% Yrs with T2D: 8.4 HbA1c: 10.8% Ethnicity: Black: 65% Ed ≤ HS: 74% Spanish: Excluded Income: 90% ≤ $40,000	None To develop and validate a newly developed knowledge scale for patients with limited literacy and with T2D (SKILLD).	Cross-sectional descriptive Questionnaire with assistance from RA	**REALM** Low (≤6th) 38% Adequate (>6th) 62%	NR SKILLD (Spoken knowledge in low literacy in diabetes scale)	**HL and Social Deter of Health:** NR **HL and SCA:** NR **HL and Inform/Motivation:** Better performance on SKILLD* **HL and HbA1c/Complications:** NR

Table 1. Health Literacy and Self-Care Activities among Patients with Type 2 Diabetes

Author, Year Title	Sample/Setting/Demographics	Theoretical Frame Purpose	Study Design Data Collection	HL Measurement HL Results	Diabetes Behavior Inform/Motivation	Significant Findings (* p<.05, ** p<.01, *** p<.001)
Seligman et al. (2005) Physician notification of their diabetes patients' limited health literacy. A randomized, controlled trial (Seligman et al., 2005)	n = 182 pts with T2DM, limited HL Primary care clinics within an urban academic public hospital Age: 63 (mean) Sex, female: 62% Yrs with T2D: NR HbA1c: 8.62% Ethnicity: Latino: 50% Black: 20% White: 8.5% Asian: 14% Ed ≤ HS: NR Spanish: 39% Income: NR	None To determine whether notifying physicians of their patients' limited HL affects physician behavior, physician satisfaction, or patient self-efficacy.	Cross-sectional randomized control intervention Self-administered questionnaire	**S-TOFHLA** Inadequate 67% Marginal 24% Adequate NR **Inad/Marg 91%**	NR Patient Enablement Instrument: physician effects on pt confidence to successfully manage chronic disease	**HL and Social Deter of Health:** NR **HL and SCA:** NR **HL and Inform/Motivation:** No sig association with SE **HL and HbA1c/Complications:** NR
Morris et al. (2006) Literacy and health outcomes: a cross-sectional study in 1002 adults with diabetes (Morris, MacLean, & Littenberg, 2006)	n = 1002 pts with T1DM or T2DM Part of the Vermont Diabetes Information System – N New Eng. Age: 66 (median) Sex, female: 54% Yrs with T2D: 6.8 (T1 or T2D) HbA1c: 7.12% Ethnicity: Latino: NR Black: NR White: 97% Ed ≤ HS: 61% Spanish: NR Income: 59% < $30,000	None To determine the association between literacy level and diabetes complications including glycemic control, systolic BP, diastolic BP and LDL.	Cross-sectional descriptive Questionnaire mailed to subjects prior to an in-home interview by RA	**S-TOFHLA** Inadequate 10% Marginal 7% Adequate 83% **Inad/Marg 17%** Mean score 29.7	NR NR	**HL and Social Deter of Health:** Less education* Lower annual income* Qualify for Medicare/Medicaid* Older age* Less likely to be married* Less likely to have private insurance* Longer duration of diabetes* **HL and SCA:** NR **HL and HbA1c/Complications:** No sig association with HbA1c

Table 1. Health Literacy and Self-Care Activities among Patients with Type 2 Diabetes

Author, Year Title	Sample/Setting/Demographics	Theoretical Frame Purpose	Study Design Data Collection	HL Measurement HL Results	Diabetes Behavior Inform/Motivation	Significant Findings (* p<.05, ** p<.01, *** p<.001)
Sarkar et al. (2006) Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy? (Sarkar, Fisher, & Schillinger, 2006)	n = 408 pts with T2DM 2 Primary Care clinics in a public hospital (San Francisco) Age: 58.1 (mean) Sex, female: 63.75% Yrs with T2D: 9.5 HbA1c: NR Ethnicity: Latino: 42%; Black: 25%; White: 15%; Asian/PI: 18%; Other: 4.5% Ed ≤ HS: NR Spanish: 36% Income: 93% < $20,000	Social Cognitive To examine the relationship between diabetes self-efficacy and self-management behavior in an urban, diverse, low-income population with a high prevalence of limited health literacy.	Cross-sectional descriptive Oral questionnaire	**S-TOFHLA** Inadequate 38% Marginal 13% Adequate 49% **Inad/Marg 52%**	Summary of Diabetes SCA Scale (SDSCA) Diabetes Self- Efficacy Scale	**HL and Social Deter of Health:** NR **HL and SCA:** Associations between self-efficacy and SM were consistent across race/ethnicity and health literacy levels. **HL and HbA1c/Complications:** NR
Cavanaugh, et al. (2008) Association of numeracy and diabetes control (Cavanaugh et al., 2008)	n = 398 pts with T2DM (86%) or T1DM 2 Primary Care & 2 Diabetes Clinics at 3 Medical Centers Tennessee & North Carolina Age: 55 (median) Sex, female: 51% Yrs with T2D: 9 (median) HbA1c: 7.2% Ethnicity: White: 63%; Non-white: 37% Ed ≤ HS: 43% Spanish: 0% Income: 44% < $20,000	None To determine the association between numeracy related to diabetes and glycemic control. In addition, other diabetes measurements were also ascertained.	Cross-sectional descriptive Patient interviews and medical record review	**REALM** Low (<9th) 31% Adequate (≥9th) 69% **WRAT-3** Low (<9th) 69% Adequate (≥9th) 31% **DNT**: Diabetes Numeracy Test Median 65%	Summary of Diabetes SCA Scale (SDSCA) Diabetes Knowledge Test (DKT) Perceived Diabetes Self-Management Scale (PDSMS)	**HL and Social Deter of Health:** Non-white*** Lower annual income*** Older age*** T2D with lower level of diabetes specific knowledge*** **HL and SCA:** NR **HL and Inform/Motivation:** Greater self efficacy of diabetes SM skills*** **HL and HbA1c:** HbA1c*

Table 1. Health Literacy and Self-Care Activities among Patients with Type 2 Diabetes

Author, Year Title	Sample/Setting/Demographics	Theoretical Frame Purpose	Study Design Data Collection	HL Measurement HL Results	Diabetes Behavior Inform/Motivation	Significant Findings (* p<.05, ** p<.01, *** p<.001)
Osborn, et al. (2009) Diabetes Numeracy: An overlooked factor in understanding racial disparities in glycemic control (Osborn, Cavanaugh, Wallston, White, & Rothman, 2009)	n = 383 pts with T2DM (85%) or T1DM 2 primary care & 2 diabetes clinics Tennessee & North Carolina Age: 56 (mean) Sex, female: 50% Yrs with T2D: 9 HbA1c: 7.2% Ethnicity: White: 65%, Nonwhite: 35% Ed ≤ HS: 43% (<HS) Spanish: Excluded Income: 44% < $20,000	None To examine the mediating effect of health literacy and numeracy (general and diabetes-related) on the relationship between African American race and glycemic control.	Cross-sectional descriptive Structured interview	**REALM** Low (<9th) 31% Adequate (≥9th) 69% **WRAT-3** Low (<9th) 69% Adequate (≥9th) 31% **DNT**: Diabetes Numeracy Test	NR NR	**HL and Social Deter of Health:** NR **HL and SCA:** NR **HL and HbA1c:** No significant relationship between HL (measured by REALM) and HbA1c. Higher diabetes-related numeracy was associated with lower HbA1c*.
Cavanaugh et al. (2009) Addressing literacy and numeracy to improve diabetes care: Two randomized controlled trials. (Cavanaugh et al., 2009)	n = 184 with T2DM (90%) or T1DM & HbA1c ≥ 7% Tennessee & North Carolina Age: 52 (median) Sex, female: 64% Yrs with T2D: 8 HbA1c: 9.1% Ethnicity: Black: 43% Ed ≤ HS: 49% (<HS) Spanish: Excluded Income: 49% < $20,000	None To evaluate the impact of a diabetes care program that included literacy and numeracy skills on HbA1c and other diabetes health outcomes.	Longitudinal intervention (data collected at baseline, 3 and 6 months)	**REALM** Low (<9th) 37% Adequate (≥9th) NR **DNT**: Diabetes Numeracy Test: Median 59%	Summary of Diabetes SCA Scale (SDSCA) Perceived Diabetes Self-Management Scale (PDSMS) Diabetes Treatment Satisfaction Questionnaire	**HL and Social Deter of Health:** NR **HL and SCA:** NR **HL and Inform/Motivation:** NR **HL and HbA1c:** NR

Table 1. Health Literacy and Self-Care Activities among Patients with Type 2 Diabetes

Author, Year Title	Sample/Setting/Demographics	Theoretical Frame Purpose	Study Design Data Collection	HL Measurement HL Results	Diabetes Behavior Inform/Motivation	Significant Findings (* p<.05, ** p<.01, *** p<.001)
Mbaezue, et al. (2010) The impact of health literacy on self-monitoring of blood glucose in patients with diabetes receiving care in an inner-city hospital. (Mbaezue et al., 2010)	n = 189 pts with T2DM or T1DM (Not clear) Large hospital-based clinic Atlanta, GA Age: 51.2 (mean) Sex, female: 58.7% Yrs with T2D: 8.5 HbA1c: NR Ethnicity: Black: 94.7% White: 5.3% Ed ≤ HS: 66.2% Spanish: Excluded Income: 78.3% < $20,000	None To examine the relationship between health literacy and self-monitoring of blood glucose (SMBG).	Cross-sectional descriptive One hour in-person interview using survey questionnaire (234 questions)	**S-TOFHLA** Inadequate 23% Marginal 16% Adequate 61% **Inad/Marg 39%**	SMBG (measured with the Diabetes Care Profile) NR	**HL and Social Deter of Health:** Older age*** Less education* Uninsured** Longer duration of diabetes** **HL and SCA:** Recording of blood sugar tests* **HL and HbA1c:** NR
Shigaki et al. (2010) Motivation and diabetes self-management (Shigaki et al., 2010)	n = 77 pts with T2DM + chronic disease Two family medicine clinics Age: 63 (mean) Sex, female: 64% Yrs with T2D: 46% dx 10+ yrs HbA1c: NR Ethnicity: Black: 21% White: 77% Other: 2% Ed ≤ HS: 32% Spanish: Excluded Income: 37% < $25,000	Self Determination To examine the relationship between autonomous motivation and diabetes self-care activities among individuals with diabetes.	Cross-sectional Descriptive Interview by RA	**NVS** Mean score = 3.7 REALM – not used for analysis (ceiling effect) Low (<9th) 17% Adequate (≥9th) 83%	SDSCA Diet adherence, BGM & exercising Treatment Self-Regulation Behavior Perceived Competence Scale	**HL and Social Deter of Health:** NR **HL and SCA:** No significant relationship between HL and self care activities. **HL and HbA1c:** NR

Table 1. Health Literacy and Self-Care Activities among Patients with Type 2 Diabetes

Author, Year Title	Sample/Setting/Demographics	Theoretical Frame Purpose	Study Design Data Collection	HL Measurement HL Results	Diabetes Behavior Inform/Motivation	Significant Findings (* p<.05, ** p<.01, *** p<.001)
Mancuso, 2010 Impact of health literacy and patient trust on glycemic control in an urban USA population. (Mancuso, 2010)	n = 102 patients T2DM (96.1%) or T1DM 2 Primary Care Clinics Urban Midwestern US City Age: 52.0 (mean) Sex, female: 60.8% Yrs with T2D: 5.8 (mean) HbA1c: 8.2% Ethnicity: Latino: 5.9% Black: 79.4% White: 12.7% Other: 2% Ed ≤ HS: 70.6% Spanish: Excluded Income: SES Scores	Self-proposed HL, Self efficacy FW To determine the relationship between health literacy, patient trust in healthcare provider, and glycemic control in an uninsured population of patients diagnosed with diabetes.	Cross-sectional predictive Both orally administered and self administered	**TOFHLA** Inadequate 15.7% Marginal 20.6% Adequate 63.7% **Inad/Marg 36.3%** Mean score: 75.9	SDSCA Diabetes Knowledge Test (DKT)	**HL and Social Deter of Health:** SES** Age* **HL and SCA:** No significant relationship between HL and SR of SCA **HL and Inform/ Motivation:** Greater diabetes knowledge** **HL and HbA1c:** No significant relationship between HL & HbA1c levels
White et al. (2011) Development and validation of a Spanish diabetes-specific numeracy measure: DNT-15 Latino (White, Osborn, Gebretsadik, Kripalani, & Rothman, 2011)	n = 144 Hispanic pts with T2DM (87%) or T1DM (3%), 10% unsure 2 FQHC Primary Care Clinics & 1 Community clinic in Nashville, TN Age: 47.8 (mean) Sex, female: 62% Yrs with T2D: 4 HbA1c: 8.1% Ethnicity: Latino: NR Mexican: 78% C/S Amer: 18% Ed ≤ HS: 91% Spanish: 100% Income: 86% < $20,000	None To (1) establish the reliability and validity of a 15-item Spanish, diabetes-specific numeracy measure (Diabetes Numeracy Test [DNT]-15 Latino) and (2) examine the relationship between diabetes-specific numeracy and diabetes-related outcomes among a sample of Latino adults with diabetes.	Cross-sectional descriptive 60-90 minute semi-structured private interview in Spanish	**S-TOFHLA** Mean score: 24.1 Inadequate 21% Marginal 15% Adequate 64% **Inad/Marg 36%** **WRAT-4** Mean score: 75.2 **Inad (≤4th) 72%** Low (5th-7th) 22% Adequate (>8th) 3% **Diabetes Numeracy Test (DNT-15)** Mean: 26.4% correct	SDSCA Diet: 3.5 Exercise: 2.0 BGM: 1.5 Foot Care: 3.5 Meds: 7.0 PDSMS Mean: 22.8	**HL and Social Deter of Health:** Acculturation level** Education level*** Income** **HL and SCA:** No significant relationship between HL & SCA **HL and HbA1c:** No significant relationship between HL & HbA1c levels

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McCleary-Jones, 2011 Health literacy and its association with diabetes knowledge, self-efficacy and disease self-management among African Americans with diabetes mellitus (McCleary-Jones, 2011)	n = 50 African Americans with T2DM (98%) or T1DM Community health center & church in Midwestern U.S. Age: 58.6 (mean) Sex, female: 76% Yrs with T1/2D: 8.7 HbA1c: 7.6% Ethnicity: Black: 100% Ed ≤ HS: 34% Spanish: Excluded Income: 68% diff pay HC	HL framework (IOM, 2004) To examine HL and its association with diabetes knowledge, perceived self-efficacy, and disease self-management among African Americans with diabetes mellitus.	Cross-sectional descriptive correlational	**REALM** Low (<9th) NR Adequate (≥9th) NR Mean score: 60.1 (7th – 8th grade level or marginal literacy)	SDSCA Diabetes Self-Efficacy Scale Diabetes Knowledge Test (DKT)	**HL and Social Deter of Health:** No significant relationship between age (no other SD reported). **HL and SCA:** Foot self-care* **HL and HbA1c:** NR
Brega et al. (2012) Mechanisms underlying the relationship between health literacy and glycemic control in American Indians and Alaska Natives (Brega et al., 2012)	n = 2594 American Indians/Alaska Natives with diabetes Participant database of Special Diabetes Prog for Indians Healthy Heart Project Age: 58% 35 – 54 yrs Sex, female: 66% Yrs with T2D: NR HbA1c: NR Ethnicity: NR Ed ≤ HS: 44.1% Spanish: NR Income: 40% < $20,000	HL FW (Paasche-Orlow 2007) To investigate the mechanisms through which HL is associated with outcomes, focusing on the relationship between HL and glycemic control among AI/ANs with diabetes.	Secondary analysis of database including 30 healthcare programs who serve Native Americans/Alaska Natives	**3 Item HL Scale** Inadequate NR Adequate NR S-TOFHLA Inadequate NR Marginal NR Adequate NR	Healthy food consumption, unhealthy food consumption, physical activity, & SMBG Diabetes Knowledge Test (DKT)	**HL and Social Deter of Health:** NR **HL and SCA:** Healthy food consumption* Unhealthy food consumption* Self-monitoring of blood glucose* **HL and HbA1c:** No significant relationship between HL & HbA1c levels

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Heinrich (2012) Health literacy: The sixth vital sign (Heinrich, 2012)	n = 54 pts with T2DM Primary care clinic Southeastern US Age: 48.3 (mean) Sex, female: 57% Yrs with T2D: NR HbA1c: NR Ethnicity: Latino: 35% Black: 43% White: 22% Ed ≤ HS: 65% Spanish: NR Income: NR	None The purpose of this project was to describe the concept of health literacy, and to assess health literacy levels in diabetic patients receiving care in primary care settings.	Cross-sectional Descriptive	**NVS** Mean score = 2.87 65% of participants obtained scores of 3 or less, indicating a strong possibility of limited literacy	NR NR	**HL and Social Deter of Health:** Education level** Race*** **HL and SCA:** NR **HL and HbA1c:** NR
Bowen et al. (2013) Numeracy and dietary intake in patients with type 2 diabetes (Bowen et al., 2013)	n = 144 pts with T2DM, HbA1c ≥ 7% Primary care clinics at Vanderbilt University Medical Center Age: 56 (median) Sex, female: 55% Yrs with T2D: 8 HbA1c: 8.3% Ethnicity: White: 66% Non-white: 33% Ed ≤ HS: 26% Spanish: Excluded Income: 22% < $20,000	None To describe the association between numeracy and self-reported dietary intake in patients with type 2 diabetes	Cross-sectional descriptive Interview by research assistant	**REALM** Low (<9th) 11% Adequate (≥9th) 89% Diabetic Numeracy Test (DNT) Median score: 67%	Dietary Intake measured with the Block FFQ NR	**HL (Numeracy) and Social Deter of Health:** Older age* Nonwhite* Female* Less than a high school education* Annual income less than $20,000* **HL and SCA:** Numeracy was not associated with dietary intake in adjusted analyses. **HL and HbA1c:** NR

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Miser et al. (2013) Clinical Utility of a Brief Screen for Health Literacy and Numeracy Among Adults With Diabetes Mellitus (Miser, Jeppesen, & Wallace, 2013)	n = 226 pts with diabetes Primary Care Clinics Ohio Age: 53.8 (mean) Sex, female: 69% Yrs with T2D: NR HbA1c: NR Ethnicity: Black: 45.1% White: 44.7% Other: 10.2% Ed ≤ HS: 45.2% Spanish: Excluded Income: NR	None To examine the clinical utility of the NVS in a sample of adults with DM. To compare and contrast patients' scores and administration characteristics on the NVS, (S)-TOFHLA and Spoken Knowledge in Low-Literacy Diabetes (SKILLD)	Cross-sectional descriptive Interview by research assistant	**NVS** Mean score = 3.2 **S-TOFHLA** Mean score = 30.7	NR NR	**HL and Social Deter of Health:** Race* Education level* **HL and SCA:** NR **HL and HbA1c:** NR
Piatt et al. (2014) Health literacy among Insulin-taking African Americans: a need for tailored intervention in clinical practice (Piatt, Valerio, Nwankwo, Lucas, & Funnell, 2014)	n = 70 African Amer with T2DM (90.8%) or T1DM and insulin-dependent Large endocrinology practice Detroit, MI Age: 58.7 (mean) Sex, female: 59.1% Yrs with T2D: 18.3 HbA1c: 8.5% Ethnicity: Black: 100% Ed ≤ HS: 41% college grad Spanish: Excluded Income: NR	None To determine the levels of functional health literacy (FHL) among insulin-taking African Americans with diabetes from an urban medical practice and to determine if associations exist between FHL levels and glycemic control.	Cross-sectional descriptive	**NVS** Mean score: 3.1 Adequate 47.1% Poss Limited 31.4% Likely Limited 21.4%	NR	**HL and Social Deter of Health:** Gender* Diabetes type* Age* Retirement status* **HL and SCA:** NR **HL and HbA1c:** HbA1c ≥ 8%*

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Al Sayah et al., 2015 Associations between health literacy and health outcomes in a predominantly low-income african american population with type 2 diabetes. (Al Sayah, Majumdar, Egede, & Johnson, 2015)	n = 343 patients with T2DM 2 Adult Primary Care Clinics South Carolina Age: 56.6 (mean) Sex, female: 68% Yrs with T2D: NR HbA1c: 8.35% Ethnicity: Black: 83.23% White: 16.77% Ed ≤ HS: 25% (less than HS) Spanish: Excluded Income: 79% < $25,000	None To determine the association between inadequate health literacy, behavioral indicators & cardio-metabolic parameters in a population of predominantly African-American patients diagnosed with T2D.	Cross-sectional Self administered	**3 Item HL Scale** Inadequate 23.9% Adequate 75.8%	SDSCA Medication Adherence Scale PDSMS Diabetes Knowledge Questionnaire	**HL and Social Deter of Health:** Education level* Race* Employment status* Insurance status **HL and SCA:** No sig relation between HL & SCA **HL and Inform/Motivation:** Greater diabetes knowledge** Diabetes self-efficacy** **HL and HbA1c:** No sig relationship between HL & HbA1c
Al Sayah et al., 2015 Association of inadequate health literacy with health outcomes in patients with Type 2 Diabetes and depression: Secondary analysis of a controlled trial (Al Sayah, Majumdar, & Johnson, 2015)	n = 154 patients with T2DM 4 Primary Care Networks Rural Alberta, Canada Age: 58.1 (mean) Sex, female: 56% Yrs with T2D: NR HbA1c: 7.6% Ethnicity: White: 94.2% Ed ≤ HS: 13.7% Spanish: NR Income: 36.1% < $40,000	None To determine the relationship bt low HL, depressive symptoms, cardio-metabolic parameters, and health-related QOL in a population of predominantly white patients diagnosed with T2D and depression.	Secondary data analysis from RCT	**3 Item HL Scale** Inadequate 16% Adequate NR Mean score: 5.9	Health-related quality of life NR	**HL and Social Deter of Health:** Male sex* **HL and SCA:** No sig relationship between HL & HRQL **HL and HbA1c/Complications:** No sig relationship between HL & HbA1c and SBP

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Author, Year Title	Sample/Setting/Demographics	Theoretical Frame Purpose	Study Design Data Collection	HL Measurement HL Results	Diabetes Behavior Inform/Motivation	Significant Findings (* p<.05, ** p<.01, *** p<.001)
Kenya et al. (2015) A profile of Latinos with poorly controlled diabetes in South Florida (Kenya et al., 2015)	n = 300 Latino pts with T2DM, HbA1c ≥ 8% Primary Care Clinics Miami-Dade County public hospital sys Age: 55.25 (mean) Sex, female: 55% Yrs with T2D: NR HbA1c: 9.31% Ethnicity: Black: 3% White: 80.5% Ed ≤ HS: NR Spanish: 100% Income: 49% < $15,000	None To describe the baseline characteristics of participants enrolled in the Miami Healthy Heart Initiative (a RCT concerning a 12 month CHW interview)	Cross-sectional descriptive	**SAHL** Inadequate NR Adequate 85%	Diet: Behavioral Risk Factor Surveillance System (Fr/Veg) Physical Activity Diabetes Distress Scale (Self-efficacy)	**HL and Social Deter of Health:** NR **HL and SCA:** NR **HL and HbA1c:** No sig relationship between HL and HbA1c
Graumlich, et al. (2016) Effects of a patient-provider, collaborative medication-planning tool: a randomized controlled trial. (Graumlich et al., 2016)	n = 674 adult pts with T2DM Outpatient clinics in Chicago & Peoria, Illinois Age: 63.6 (mean) Sex, female: 56% Yrs with T2D: 9.4 HbA1c: 8.05 Ethnicity: White: 64% Black: 30% Other: 16% Ed ≤ HS: 31% Spanish: Excluded Income: 23% < $20,000	Process-Knowledge To test the effectiveness of a medication-planning tool designed to improve patients medication knowledge, adherence & glycemic control.	Randomized controlled multi-site trial Questionnaire	**REALM** Low (<9th) 22% Adequate (≥9th) 78% Mean score: 61.2	SDSCA Medication Adherence Scale Diabetes Knowledge Questionnaire	**HL and Social Deter of Health:** NR **HL and SCA:** Relationship between HL and medication adherence was not reported, but baseline scores did differ among different HL levels. **HL and HbA1c:** NR

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Smith-Miller, et al. (2016) Type 2 Diabetes Self-management Among Spanish-Speaking Hispanic Immigrants (Smith-Miller, Berry, DeWalt, & Miller, 2016)	n = 30 Spanish-speaking Hispanic Immigrants with T2DM Grocery stores, churches, community centers in North Carolina Age: 27-86 (range) Sex, female: 64% Yrs with T2D: NR HbA1c: 7.7 Ethnicity: Mexican: 90%, Other Latin: 10% Ed ≤ HS: Mean yrs: 7.2 Spanish: 100% Income: NR	Social Cognitive To examine the relationship among knowledge, self-efficacy, health promoting behaviors, and T2D self-management among recent Spanish-speaking, limited English proficient immigrants to the US.	Cross-sectional descriptive Interview by research assistant	**Short Assessment of Health Literacy for Spanish Speaking Adults (SAHLSA)** Diabetes Knowledge Test (DKT)	Health-Promoting Lifestyle Profile II (HPLP-II) Diabetes Self-Efficacy	**HL and Social Deter of Health:** NR **HL and SCA:** NR **HL and HbA1c:** NR

T2DM: Type 2 Diabetes, SR: Self Report, HbA1c: Hemoglobin A1C, DR: Diabetic Retinopathy, SM: Self-management, NR: Not Reported, SCA: Self-Care Activities

THEORETICAL FRAMEWORKS USED IN T2DM HL SCA INQUIRY

Among studies aiming to establish a link between health literacy and SCA and health outcomes among patients with T2DM, less than a third identified a theoretical basis for the design of the study. Among studies that did identify a theoretical framework, only two authors agreed and used the Social Cognitive Theory (Sarkar et al., 2006; Smith-Miller et al., 2016). Two others utilized a health literacy framework – the IOM HL framework (McCleary-Jones, 2011) and Paasche-Orlow's 2007 HL framework (Brega et al., 2012). One used the Theory of Self-Determination (Shigaki et al., 2010) and another, the Process-Knowledge Theory (Graumlich et al., 2016). Finally, one of the authors proposed a new theory linking self-efficacy and HL (Mancuso, 2010). The lack of consensus among researchers regarding theoretical framework, definitions of key variables and pathways among relevant variables often results in inconsistent findings and ultimately, an inability to find meaningful mediators that influence SCA in T2D populations. Therefore, this study will test a more generalizable theoretical framework that incorporates information, motivation, and behavioral variables relevant to T2DM SCA.

HEALTH LITERACY INSTRUMENTATION IN T2DM HL SCA INQUIRY

Among included studies, the most commonly used health literacy instrument was the REALM, with 8 studies reporting its use (Bowen et al., 2013; Cavanaugh et al., 2008; Cavanaugh et al., 2009; Graumlich et al., 2016; McCleary-Jones, 2011; Osborn et al., 2009; Rothman et al., 2004; Rothman et al., 2005). The Rapid Estimate of Adult Literacy in Medicine (REALM) is a list of 66 words used commonly in the healthcare system that

is presented to the participant to be read aloud in a consecutive manner (Davis et al., 1993). The score is reported either as a continuous measure 0 to 66 (raw score), or as a categorical measure (0 to 19 = 3rd grade and below, 19 to 44 = 4th to 6th grade, 45 to 60 = 7th to 8th grade, 61 to 66 = 9th grade or above). The REALM scores were often dichotomized into two groups: less than 9^{th} grade reading level (adequate) or $\geq 9^{th}$ grade reading level (inadequate).

Equal to REALM in prevalence, the S-TOFHLA was used as a measure of health literacy in 8 studies (Kim et al., 2004; Mbaezue et al., 2010; Miser et al., 2013; Morris et al., 2006; Sarkar et al., 2006; Schillinger et al., 2002; Seligman et al., 2005; White et al., 2011) and one used the long form of the same instrument, the TOFHLA (Mancuso, 2010). The Short Test of Functional Health Literacy in Adults (S-TOFHLA), a measure of functional health literacy, is a 36-item test of a patient's ability to read information commonly presented in a health care setting, using a modified Cloze procedure. The reading passages are taken from a Medicaid application form and instructions for preparation for an upper GI series (Baker, Williams, Parker, Gazmararian, & Nurss, 1999; Parker, Baker, Williams, & Nurss, 1995). Scores range from 0 – 36 and can be reported as a continuous measure or as a categorical measure (0 – 16 = inadequate HL, 17 – 22 = marginal HL, 23 – 36 = adequate HL). Those who exhibit marginal or inadequate functional HL may have difficulty understanding and interpreting most health information on printed materials.

Typically citing and testing clinical utility, 4 studies used the NVS to measure health literacy (Heinrich, 2012; Miser et al., 2013; Piatt et al., 2014; Shigaki et al., 2010).

The Newest Vital Sign is a test of functional health literacy, requiring both literacy and numeracy skills from the participant (Weiss et al., 2005). The NVS presents patients with a nutrition label from a container of ice cream and the facilitator then asks them six questions about the content on the label, with each correct answer earning one point (0 – 6). The likelihood of limited literacy/numeracy is based on the number of correct answers on the NVS: 0 – 1 (likely), 2 – 3 (possible) and 4 – 6 (unlikely). Scores for the NVS are usually reported as dichotomous variables: either "likely to have limited literacy" (scores of 0 - 3) or "unlikely to have limited literacy" (scores of 4 - 6).

Three studies utilized the 3-Item HL Scale (Al Sayah et al., 2015; Al Sayah et al., 2013; Brega et al., 2012). This brief health literacy screening tool addresses print literacy and consists of 3 questions that assess self-reported confidence in reading and completing medical forms (Chew, Bradley, & Boyko, 2004). The three questions include: (1) *How often do you have problems learning about your medical conditions because of difficulty understanding written information?;* (2) *How confident are you filling out medical forms by yourself?;* (3) *How often do you have someone help you read hospital materials?*. The questions are scored on a 5-point Likert scale. The three questions are scored as dichotomous items (inadequate = responses of sometimes, occasionally, never).

The Short Assessment of Health Literacy for Spanish-speaking Adults (SAHLSA) was used in two studies targeting Spanish-speaking participants (Kenya et al., 2015; Smith-Miller et al., 2016). SAHLSA is a screening tool modeled after the REALM, but culturally modified for Latino populations (Lee, Bender, Ruiz, & Cho, 2006). In addition, this tool uses 50 words as opposed to 66 in the REALM, in addition to questions to assess

comprehension of each word. Scores range from 0 – 50 and can be reported as a continuous measure or as a dichotomous categorical measure (0 – 37 = inadequate HL, 38 – 50 = adequate HL).

Several of the studies included a measure of numeracy skills, in addition to a health literacy measure. Two numeracy tests were included in this collection of studies: the Wide Range Achievement Test and the Diabetes Numeracy Test. Five studies incorporated the Diabetes Numeracy Test (DNT-15) as a measure of numeracy skills (Bowen et al., 2013; Cavanaugh et al., 2008; Cavanaugh et al., 2009; Osborn et al., 2009; White et al., 2011). The DNT-15 is a short written test to assess diabetes-specific numeracy skills. There are five diabetes self-management domains included in the DNT-15 and those are nutrition, exercise, blood glucose monitoring, oral medications and insulin administration (Huizinga et al., 2008). The score is calculated as a percentage correct out of 100 and is often reported as a mean score in sample data results. Three studies incorporated the use of the math portion of the Wide Range Achievement Test, 3rd or 4th edition (Cavanaugh et al., 2008; Osborn et al., 2009; White et al., 2011). The WRAT is a validated instrument that evaluates calculation skills and general numeracy skills (Wilkinson, Robertson, & Psychological Assessment Resources Inc., 2006). Scores are categorized by grade equivalence and reported as categorical data (inadequate: $\leq 4^{th}$ grade, low: $5^{th} – 7^{th}$ grade, adequate: $\geq 8^{th}$ grade).

In summary, the three most common instruments used to measure health literacy and numeracy in this collection of studies includes the REALM, S-TOFHLA, and the NVS. While these three instruments all claim to measure the same construct, they differ

greatly by administration method, administration time, difficulty, scoring, and result reporting (Table 2). Therefore, participant data regarding health literacy should be carefully interpreted during synthesis reporting. In addition, without consensus among researchers concerning how best to measure HL within this population, the science will be slow to advance. After careful examination of each health literacy measurement tool, the NVS and a modified version of the REALM (DM-REALM) were chosen for this study. The NVS was chosen because it: (1) incorporates the use of a nutrition label – information that should be familiar to patients with T2D, (2) measures both elements of functional health literacy – numeracy and literacy, (3) is administered in a short amount of time and (4) was designed for clinical use. The DM-REALM was chosen because it (1) uses a list of diabetes-specific words and (2) measures oral/spoken literacy. Together, these two health literacy instruments address important elements of health literacy.

Table 2. Comparison of REALM, S-TOFHLA, and NVS

Instrument	Admin Method	Num of Items	Admin Time	Scoring	Result Reporting	Limited HL
REALM	In-person interview List of words read aloud	66 words	2 – 3 minutes	0 – 18	3rd grade or below	Limited
				19 – 44	4th to 6th grade	Limited
				45 – 60	7th to 8th grade	Limited
				61 – 66	$\geq$ 9th grade	Adequate
S-TOFHLA	Self-administered 2 reading passages Cloze procedure	36 items	7 minutes	0 – 16	Inadequate	Limited
				17 – 22	Marginal	Limited
				23 – 36	Adequate	Adequate
NVS	In-person interview Nutrition label Oral questions	6 questions	3 minutes	0 – 1	High likelihood of limited literacy	Limited
				2 – 3	Possibility of limited literacy	Limited
				4 – 6	Adequate literacy	Adequate

HEALTH LITERACY & SOCIAL DETERMINANTS OF HEALTH

To better understand how social determinants of health correlate with health literacy among people with T2DM, data was extracted from each study regarding age, race, income, education attainment, primary language and any other social factors. Fifteen of the 25 studies included in this literature review reported correlations between HL and social determinants of health. Age was found to have a significant correlation to health literacy in nine of the fifteen studies (Bowen et al., 2013; Cavanaugh et al., 2008; Kim et al., 2004; Mancuso, 2010; Mbaezue et al., 2010; Morris et al., 2006; Piatt et al., 2014; Rothman et al., 2004; Schillinger et al., 2002) as well as education attainment (Al Sayah et al., 2015; Bowen et al., 2013; Heinrich, 2012; Kim et al., 2004; Mbaezue et al., 2010; Miser et al., 2013; Morris et al., 2006; Schillinger et al., 2002; White et al., 2011). Race was found to be a significant correlate of HL in 7 studies (Al Sayah et al., 2015; Bowen et al., 2013; Cavanaugh et al., 2008; Heinrich, 2012; Miser et al., 2013; Rothman et al., 2004; Schillinger et al., 2002), while income exhibited an effect on HL in six studies (Bowen et al., 2013; Cavanaugh et al., 2008; Kim et al., 2004; Morris et al., 2006; Rothman et al., 2004; White et al., 2011). Finally, gender was found to be a significant correlate to HL in 3 studies (Al Sayah et al., 2015; Bowen et al., 2013; Piatt et al., 2014) and acculturation level or English-speaking ability was related to HL in 2 studies (Schillinger et al., 2002; White et al., 2011).

Echoing results from other studies, the social determinants of health are closely related to health literacy and should be an important consideration in HL study design. Therefore the relationship between health literacy, age, gender, language, acculturation,

income, employment, housing type, education attainment, marital status, years with T2DM and insurance type will be examined in this study.

Health Literacy and Diabetes Self-Efficacy

Among these studies, nine measured and reported the level of self-efficacy among study participants (Al Sayah et al., 2015; Cavanaugh et al., 2008; Cavanaugh et al., 2009; Kenya et al., 2015; McCleary-Jones, 2011; Sarkar et al., 2006; Shigaki et al., 2010; Smith-Miller et al., 2016; White et al., 2011). Among them, five different tools were used to measure self-efficacy. Four reported the use of the Perceived Diabetes Self-Management Scale – PDSMS (Al Sayah et al., 2015; Cavanaugh et al., 2008; Cavanaugh et al., 2009; White et al., 2011) and three used the Diabetes Self-Efficacy Scale (McCleary-Jones, 2011; Sarkar et al., 2006; Smith-Miller et al., 2016). Shigaki et al. (2010) used both the Treatment Self-Regulation Behavior and Perceived Competence Scale to measure self-efficacy. Acknowledged only once among this selection of studies, Kenya et al. (2015) utilized the Diabetes Distress Scale as a measurement of self-efficacy. Although self-efficacy scores were measured and reported in these studies, only two study authors reported any findings related to self-efficacy. In one, greater self-efficacy was significantly and positively related to diabetes self-management skills (Cavanaugh et al., 2008), while in the other, diabetes self-efficacy was significantly and positively correlated with health literacy (Al Sayah et al., 2015). This inconsistency in reporting of analysis results related to self-efficacy implies further research may be necessary.

HEALTH LITERACY AND DIABETES KNOWLEDGE

Studies have reported that higher levels of health literacy positively and significantly correlate with better knowledge of diabetes (Al Sayah et al., 2015; Kim et al., 2004; Mancuso, 2010; Rothman et al., 2005). Instruments to measure diabetes knowledge vary across similar studies. The Diabetes Knowledge Test, or DKT is used frequently to measure diabetes-related knowledge among study participants (Brega et al., 2012; Cavanaugh et al., 2008; Mancuso, 2010; McCleary-Jones, 2011). Similarly, the Diabetes Knowledge Questionnaire (DKQ) was also used to measure diabetes knowledge among study participants (Al Sayah et al., 2015; Graumlich et al., 2016; Kim et al., 2004). An additional tool called the Spoken Knowledge in Low Literacy in Diabetes Scale, or the SKILLD is also reported in the literature (Rothman et al., 2005). Diabetes related knowledge is an essential element of diabetes SCA and there are a variety of measurement methods available for research. A review of existing literature revealed that the Diabetes Knowledge Test was the most frequently used measure of participant knowledge and therefore, was chosen as the instrument for this study.

SUMMARY

The findings from this literature review suggest that while a growing number of researchers argue HL has a critical role in SCA among people with diabetes (Brega et al., 2012; Cavanaugh et al., 2008; Mbaezue et al., 2010; McCleary-Jones, 2011), that relationship is not always consistently recognized. Specifically, several studies failed to capture the direct effect of HL on SCA (Al Sayah et al., 2015; Bowen et al., 2013; Kim et al., 2004; Mancuso, 2010; Osborn et al., 2009; Sarkar et al., 2006; Schillinger et al.,

2002; Shigaki et al., 2010; White et al., 2011). Lack of homogeneity among sample attributes, study design, choice of theoretical framework and health literacy instrument makes it difficult to generalize these research findings. Several methodological considerations should be considered in order to reconcile the seemingly valid theoretical propositions regarding the positive effect of HL on SCA.

In addition, most of the research regarding HL and T2DM SCA was not guided by a theoretical model. This lack of framework fails to appropriately identify a plausible pathway of how HL may influence SCA and/or outcome variables. Also, a great majority of authors used a global HL measurement rather than a diabetes-specific HL measurement. Finally, few studies examined the role of HL in priority populations that traditionally suffer from low HL such as people living in states along the US – Mexico border, non-English speakers, and those at the highest risk of poverty.

These scientific gaps in the field highlight the need and direction of future research. The following are the key areas of methodological areas that future research should fulfill; 1) a lack of theoretical framework that specify the pathway of HL influencing SCA for the respective target population, 2) limited sensitivity and specificity of HL measures along with cultural relevancy for the respective target population, and a lack of research that explicate the differential roles of HL in populations struggling with important social determinants of health such as poverty and language barriers.

The findings of this literature review identified several methodological gaps in the state of health literacy science and health disparity research. These methodological gaps in the field have both research and practice implications. It seems the level of individual

HL often influences clinical outcome (e.g.HbA1c) indirectly through several mediators rather than exerting direct influence on them. The studies that are not guided by a comprehensive theoretical framework more likely offer erroneous conclusions of a null relationship between HL and/or SCA or improved clinical outcomes. In addition, current diabetes researchers appear to not always pay close attention to the specific qualities of the selected HL measure (e.g., sensitivity and specificity) and fail to align them with other variables within the study. For example, as the majority of diabetes researchers use global HL measure rather than a diabetes-specific HL measure, the built in discrepancy of the levels of specificity among variables can also contribute potentially erroneous conclusions and decelerate the progress of HL science.

Ultimately, the limited progress of health literacy science prevents researchers and clinicians from developing and implementing potentially effective HL focused interventions. Specifically, few clinicians and researchers have attempted to directly influence HL levels as a means of improving the ability to manage chronic diseases such as diabetes. Previous intervention studies involving individuals with low HL have predominantly focused on adjustment of reading levels in written educational materials or incorporating the use of video, audiotapes, and other technology to accommodate HL deficits.

Future HL research that sheds light on finding a comprehensive theoretical framework that identifies meaningful mediators and pathways between HL and SCA is sorely needed. The findings of such studies will also pose strong implications for health disparity research. Given that many people with limited HL are likely to face serious

consequences of other social determinants of health such as low education and income, they often suffer from low self-confidence and/or depression. Moreover, the adverse effect of low HL is more salient among low income, foreign-born, non-English speakers. In addition, limited health literacy has been found to be a strong predictor of inadequate utilization of health care resources in many of these vulnerable immigrant populations. Constructing innovative ways to improve HL is a potentially fruitful intervention for not only improving self-care activities and outcomes but also for improving self-confidence by empowering these individuals through HL skill building activities. In conclusion, this literature review identified several important methodological gaps and opportunities for future research and potential interventions to propel health disparity research and practice.

Chapter Three: Methods

The purpose of this chapter is to describe the study design, inclusion and exclusionary criteria of the sample, size determination of the sample, the setting, and procedures related to data collection. Additionally, detailed descriptions of the instruments used in this study, as well as the plan for data analysis for each research question will be discussed.

RESEARCH DESIGN

A correlational, descriptive cross-sectional design with multivariate analysis will be used for the proposed research. The data of this study is obtained from a health literacy surveillance study of a Federally Qualified Health Center (FQHC) led by Dr. Miyong Kim in 2015 (Kim, Ko, Murry, Lee & Baik, 2016). This dissertation study will focus on examining potential relationships among theoretically relevant variables in the context of explicating the role of health literacy and self-care activities among underserved patients with T2DM.

Although secondary analysis is often performed by a researcher who may not have actively participated in the design or data collection aspects of the original study, the author of this dissertation was involved in the original study from beginning to end. She began by participating in multi-disciplinary meetings related to design of the survey, then helped to select pertinent constructs, and also contributed to questionnaire design. Additionally, she was the project manager for the study which included the recruitment, hiring and training of RAs, development of a coordinated plan to collect data, implementation of the data collection schedule, management of the data collection

process, as well as the maintenance of confidentiality and proper storage of all collected data.

SETTING

Patients with limited education attainment, low income, and limited English proficiency are at the highest risk of limited health literacy (IOM, 2004). In order to create an ideal sample to examine the proposed research questions, the study team collaborated with the largest Federally Qualified Health Center (FQHC) network in central Texas. FQHCs serve as important safety nets in the community by providing outpatient healthcare services to the most vulnerable patients affected by poverty (Centers for Medicare and Medicaid Services, 2018). FQHCs are healthcare centers, community clinics, or hospitals that provide care for underserved areas or populations. In return, FQHCs qualify for both special funding under the Public Health Service Act and enhanced reimbursement from Medicare and Medicaid. FQHCs are required by HRSA (Health Resources and Services Administration) to offer a sliding fee scale to patients, maintain an ongoing quality assurance program and uphold a governing board of directors, 51% of which must be current patients (U.S. Department of Health & Human Services, CMS, 2017). This study was partnered with CommUnityCare Health Centers (CUC), the largest FQHC serving Travis County. CUC provides primary care healthcare services to over 88,000 patients within 19 clinics across Travis County (CommUnityCare, 2016).

POPULATION

Patients who choose to seek medical care from an FQHC, such as

CommUnityCare Health Centers (CUC), do so most often because they are uninsured, underinsured and/or have a household income at or below the federal poverty level. Although a small percentage of patients seeking care from CUC use private insurance benefits (approximately 10%), the vast majority of patients rely on federal, state, and/or county assistance to pay for their healthcare needs (CommUnityCare, 2016). In Travis County, there are four main health benefit programs that supplement the costs of medical care for patients within this FQHC: Medicaid, Medicare, Medical Access Program, and a sliding scale program. Unique to Travis County is the Medical Access Program (MAP), which is funded by Central Health (a local tax-supported entity), and covers expenses for primary care, prescriptions and hospitalization for Travis County citizens that do not qualify for any other health benefit programs. Many of the patients served by CommUnityCare live in poverty, as defined by the federal government.

Poverty guidelines are a federal poverty measure upheld each year in the Federal Register by the Department of Health and Human Services (HHS). Historically referred to as the "federal poverty level", determination of financial eligibility for many federal, state, and locally funded services now rely on "poverty guidelines". Patient eligibility is determined by an annually published chart from the federal government and is based on the number of persons in the family/household. For a single person, the federal poverty guideline (FPG) is an annual household income of $12,060; for a family of 4, the FPG is $24,600 and for a household with 8 people, the FPG is $41,320 (U.S. Department of Health & Human Services, 2017). The qualification process for each type of assistance varies, but all are based on FPG.

Although the city of Austin and Travis County are often thought of as resource rich, there are many areas of the county where families continue to live in poverty. As many neighborhoods undergo gentrification, the income gap continues to widen between the rich and the poor. There are an estimated 275,722 families living in Travis County in 2017. Twelve percent of those families (33,061) are living in poverty. The highest concentration of Travis County families living in poverty are located to the north, east and south of the city center (Central Health, 2017).

In addition to the income disparity, there also exists an ethnic disparity in these underserved regions of the county. Although Hispanics and Latinos account for 32.5% of Travis County's overall population, they represent 58.5% of the population in the high-poverty and moderate-poverty census tracts. The White demographic, which is the largest race/ethnicity in Travis county (48.9%), account for the second highest concentrations of poverty level at 19.6% of the population. However, none of the nine identified census tracts highlighted for poverty met or exceeded the county's overall rate of White residents. Representing 8% of Travis County residents, African Americans are the third largest demographic group of residents living in poverty, representing 13% of the population. Asian residents account for 6.4% of the counties population, but just 4.3% of the population are living in poverty (Central Health, 2017).

After studying the patients' demographic information with investigators from CUC and in an effort to gain more diverse data, six clinics were selected as they serve patients that have the most representative demographic characteristics (e.g., socio-demographic status, numbers and kinds of chronic illness, and ethnic make-up). The six

clinics are located in a variety of locations across Travis County. Central Health has identified nine impoverished regions of Travis County. The clinics included in this study serve six of the nine identified poverty regions. More detailed information regarding the location, payer mix, total number of patients and top five diagnostic codes are provided in Table 3.

Table 3. *FQHC clinic location, payer mix & diagnostic codes (2016)*

Travis County Region	**Payer Mix**		**Top 5 Diagnostic Codes**
Far Northeast	MAP	21.67%	Essential (primary) hypertension
	Medicaid	24.93%	Disorders of lipoprotein metabolism and other lipidemias
	Medicare	8.99%	Encounter for general examination without complaint, suspected or reported diagnosis
	Sliding Scale	18.55%	**Type 2 diabetes mellitus**
	Commercial	22.10%	Encounter for screening for malignant neoplasms
North Central	MAP	20.74%	Encounter for general examination without complaint, suspected or reported diagnosis
	Medicaid	30.91%	Essential (primary) hypertension
	Medicare	7.09%	**Type 2 diabetes mellitus**
	Sliding Scale	23.28%	Disorders of lipoprotein metabolism and other lipidemias
	Commercial	10.37%	Encounter for supervision of normal pregnancy
Northeast	MAP	23.08%	Encounter for general examination without complaint, suspected or reported diagnosis
	Medicaid	31.69%	Essential (primary) hypertension
	Medicare	2.29%	Disorders of lipoprotein metabolism and other lipidemias
	Sliding Scale	17.25%	**Type 2 diabetes mellitus**
	Commercial	20.12%	Encounter for screening for other diseases and disorders

Table 3, cont. *FQHC clinic location, payer mix & diagnostic codes (2016)*

East	MAP	29.13%	Essential (primary) hypertension
	Medicaid	25.25%	**Type 2 diabetes mellitus**
	Medicare	8.85%	Encounter for general examination without complaint, suspected or reported diagnosis
	Sliding Scale	23.90%	Disorders of lipoprotein metabolism and other lipidemias
	Commercial	8.77%	Other anxiety disorders
South	MAP	24.68%	Essential (primary) hypertension
	Medicaid	25.45%	Encounter for general examination without complaint, suspected or reported diagnosis
	Medicare	7.24%	**Type 2 diabetes mellitus**
	Sliding Scale	19.34%	Encounter for supervision of normal pregnancy
	Commercial	9.63%	Encounter for contraceptive management
Southeast	MAP	31.31%	Essential (primary) hypertension
	Medicaid	22.06%	**Type 2 diabetes mellitus**
	Medicare	6.59%	Encounter for general examination without complaint, suspected or reported diagnosis
	Sliding Scale	23.96%	Disorders of lipoprotein metabolism and other lipidemias
	Commercial	10.56%	Abdominal and pelvic pain

SAMPLE

Using the number of patients who used these six clinics and had one or more chronic illness, we conducted the survey using random selection from a list of patients with type 2 diabetes identified by CUC. Inclusion criteria included: 1) enrolled patients at CUC Health Centers; 2) aged 18 or older; 3) medical diagnosis of type 2 diabetes with at least one measurement of HbA1c within the last year; 4) able to speak English or Spanish and 5) expressed willingness to participate in all aspects of the study. Exclusion criteria included: 1) an unwillingness or inability to complete all questionnaires.

Sample Size Determination

The original study was designed to explore relationships among the level of health literacy, SCA and glucose control. In a non–experimental design, power estimation and sample calculation is often not based on arbitral effect size(s). However, for this study, a power analysis to determine if the sample size was large enough to predict diabetes self-care activities was undertaken. The power analysis revealed that with an alpha of 0.5, power of .90 and effect size of .35 (using multiple regression), the final sample size (n = 388) was more than adequate to yield valid results with sufficient power.

PROCEDURES

Sampling

This study was designed collaboratively with the Chief Operating Officer of CUC. Sampling procedures were discussed at length and due to the breadth of data collected at multiple sites across the city, it was agreed that a singular method of recruitment would be appropriate. CUC agreed to provide a comprehensive list of all patients with T2D at each one of the six clinics where recruitment would take place. Each week, the study project manager was sent a list of appointments for the upcoming week and the appointment list was compared with the existing list of patients with T2D. All eligible patients were identified with color-coding and the list was provided to clinic check-in staff (office clerks). If confirmed as eligible, the study was explained briefly by clinic staff, and individuals were asked if they were interested in participating in the survey during the check-in process. For those who expressed interest, the bilingual RA from the research team used a project recruitment protocol to confirm eligibility. Using a

script to ensure standardization, the trained RA explained that the interview would last about 30 minutes and would be conducted in a private area in the clinics. If the answer was affirmative, the RA coordinated with clinic staff and the patient an appropriate time for the interview.

Data Collection

Usually, and as clinic wait times for the patient could be lengthy, the interview would take place during the waiting period for the patient and was coordinated closely with clinic staff. If the patient did not have enough time before their appointment with the healthcare provider, the interview was scheduled immediately following their appointment with their consent.

All RAs were bilingual in both English and Spanish (confirmed by oral conversation with native Spanish-speaking Associate Professor at the School of Nursing). Language preference was confirmed immediately with patient what language they preferred to speak or complete the survey. Before data collection began, the RA asked the following question to determine their eligibility for the study: "Have you been diagnosed with Type 2 Diabetes by a doctor?" This double-check was employed as the information entered into a medical chart can be incorrect. If the patient was eligible based on their affirmative response, the RA explained the study and a written informed consent was obtained. The informed consent form (Appendix A-2 and A-3), Health Insurance Portability and Accountability Act documentation (HIPAA form; Appendix A-4 & A-5) and all study materials were provided in both English and Spanish language forms.

Completion of the survey took approximately 30 minutes, including the consent and HIPAA forms. Every participant was interviewed for the first section of the survey using each of the health literacy instruments (the Newest Vital Sign and the DM-REALM), and the RA would instruct the patient to complete the rest of the questionnaire while they sat nearby. Each RA was trained to detect difficulties with literacy. If the RA determined that the patient was having difficulty reading the survey questions, the RA would offer to complete the questionnaire orally (interview style). As a primary community partner organization, CUC shared the programmatic and managerial responsibility with the investigators and was responsible for providing the facilities for data collection and recruiting participants. Quiet, private spaces to conduct the interviews were provided at each clinic location.

PROTECTION OF HUMAN SUBJECTS

Permission for the original study and this secondary analysis was obtained from the University of Texas at Austin Institutional Review Board (Appendix A-1 and A-6) and the School of Nursing Department Review Committee. In addition, and as required by CUC, permission was also received from the Human Rights Committee at the study site. Each participant in the study was provided information regarding the purpose and procedures of the study, their rights as participants, protection of their privacy, measures to ensure confidentiality, the risks and benefits of participation in the study and several ways to contact the principal investigator with questions or concerns. This information was provided in English or Spanish, depending on their stated language preference. After completion, surveys were physically transported daily to the research office and stored in

a locked file cabinet. A running log of participant medical record numbers and survey unique ID number was kept to link information from the participant's medical record to their survey in the electronic database. This log linking MR and survey numbers was kept separately from all other study documents to ensure confidentiality of information.

MEASUREMENT

The instruments used in this study included the following: 1) Personal Characteristics; 2) NVS; 3) DM-REALM; 4) Michigan Diabetes Knowledge Test; 5) Seven questions regarding Health Information-Seeking Behaviors; 6) Stanford Self-Efficacy for Managing Diabetes Scale; and 7) Summary of Diabetes Self-Care Activities scale. All survey questions, including each of the listed instruments, were administered in either English or Spanish, depending on the participant's language preference. All Spanish translations were verified by native Spanish speaking faculty at the School of Nursing.

Personal Characteristics

Participant data were collected regarding self-reported age, gender, language, acculturation, income, employment, housing type, education attainment, marital status, years with T2DM and insurance type (Appendix C-3).

Health Literacy

Health literacy was assessed using two instruments - the NVS and the DM-REALM. Both instruments are available in English and Spanish and were offered to participants dependent on their language preference. The NVS is an instrument used to measure functional health literacy as the items of the tool measure one's numeracy skills

as well as print literacy and document literacy. The NVS consists of a nutrition label for a container of ice cream accompanied by 6 interviewer-led questions about the information they can derive from reading the label (Weiss et al., 2005). The nutrition label is a familiar tool for most people in the U.S. and should be an important part of dietary management, especially among people with diabetes. It is for this reason that the NVS was chosen as the instrument to measure health literacy over other commonly used health literacy tools such as the S-TOFHLA (Short-Test of Functional Health Literacy in Adults). The task requires that participants have facility with both reading and numeracy in order to answer the questions correctly. Sample items include "If you eat the entire container, how many calories will you eat?" and "Pretend that you are allergic to peanuts. Is it safe for you to eat this ice cream?" (one of the ingredients on the label is peanut oil). The NVS has been used successfully in other T2DM self-care studies (Heinrich, 2012; Miser et al., 2013; Piatt et al., 2014; Shigaki et al., 2010) and was developed for use in primary care settings (Weiss et al., 2005).

The NVS takes about 3 minutes to administer, but there is no time limit for participants to answer the questions. Questions 1 – 4 assess numeracy skills, while questions 5 and 6 assess literacy skills of the participant. The scores can be categorized into three levels of health literacy: 0 – 1 correct answers suggests a high likelihood of limited health literacy, 2 – 3 correct answers suggests a possibility of limited health literacy and respondents who get 4 or more questions correct are considered to have adequate health literacy.

The NVS is available in both English and Spanish (Appendix C-1). Reliability and validity for both the English and Spanish version were tested by the original author (Weiss et al., 2005) using the results from a sample of 500 participants (250 English speakers & 250 Spanish speakers). The internal consistency of both versions was good with a Cronbach's alpha of 0.76 for the English version and 0.69 for the Spanish version. Criterion validity was determined by calculating the correlation between the scores on the NVS and the TOFHLA. Both language versions were significantly and positively correlated with the TOFHLA; English NVS and TOFHLA ($r = 0.59$, $p < .001$) and Spanish NVS and TOFHLA ($r = 0.49$, $p < .001$).

The DM-REALM is a newly adapted instrument based on the original REALM. Details about the development of this tool are available in a separate manuscript (Kim et al., 2018). The original REALM instrument was developed by Davis et al. (1993) and consists of 66 common medical words and lay terms for body parts. Participants are asked to recite each of the words on the list. It does not require any mathematical skills. Scores are typically dichotomized into two categories: 1) scores of 0 – 60: less than 9th grade reading level and 2) scores of 61 – 66: 9th grade reading level and above. The DM-REALM consists of 82 diabetes-specific words. The DM-REALM requires the participant to read and recite words related to diabetes management. Using the original REALM instrument score ranges as a guide (Davis et al., 1993), scores were dichotomized into two groups: scores ranging from 0 to 75 indicated inadequate oral health literacy and scores above 76 indicated adequate oral health literacy. The resulting scores of the DM-REALM may indicate two things: 1) the participant's literacy level and

2) the participant's comfort level with diabetes-associated words. When a participant is unable to pronounce a word correctly, they were asked to skip to the next word they recognized. The participant would receive one point per correctly annunciated word. This instrument is available in both English and Spanish (Appendix C-2). Reliability and validity on this instrument are currently being undertaken by Kim et al. (2018). However, preliminary results of the analysis reveal a Cronbach's alpha of 0.98 and a positive correlation with the NVS ($r = 0.49$, $p < .001$).

Diabetes Knowledge

Diabetes knowledge was assessed using the Michigan Diabetes Knowledge Test (MDKT), which has two sets of questionnaires: a 14-item general test and a 9-item insulin-use subscale (Fitzgerald et al., 1998). The test is multiple-choice and consists of questions related to diabetic nutrition (carbohydrate and fat content), testing of blood glucose, signs and causes of hypo/hyperglycemia, adverse physiological effects of diabetes, foot care, and medication management (Appendix C-5). The test takes approximately 10 minutes to complete. To accommodate the possibility of low literacy skills among study participants, we chose to add one additional choice to each question not present in the original version: "Don't know". The knowledge score is determined by giving one point for each correct answer and zero for the wrong answer, no response or an answer of "Don't know". Those who get the highest scores are the most knowledgeable about diabetes. Due to the low number of insulin users in this study and missing data, only the first 14 questions were used for this study. The total knowledge scores ranged from 0 to 14 with higher scores indicating a higher level of general

diabetes knowledge. Reliability of the measure is good as the coefficient alphas were found to be 0.77 for the first 14 questions and 0.84 for the remaining nine insulin questions. Validity testing revealed patients with T1D produced a higher score on the general test and insulin subscale when compared to patients with T2D (Fitzgerald et al., 1998).

Health Information-Seeking Behaviors

Maibach et al. (2006) analyzed data from the Porter Novelli's HealthStyles 1999 and 2003 databases (Appendix C-6). They measured health information-seeking behaviors, but because they used these items within a larger cluster analysis, no composite index was computed and thus, no α was reported. The seven items were:

1. *I don't have time to bother learning a lot of health information.*
2. *I make a point to read/watch stories about health.*
3. *I don't pay attention to health information unless it's about a problem I have.*
4. *When sick, I try to get information about my disease.*
5. *I like to get health information from a variety of sources.*
6. *When I take medicine, I try to get as much information about benefits and side effects.*
7. *Before making a decision about my health, I find out everything I can about this issue.*

Each item was measured on a 1-5 Likert scale, where 1 = *Strongly Disagree* and 5 = *Strongly Agree*.

The HISB instrument was assessed for psychometric properties. The reliability was evaluated based on Cronbach's alpha coefficients, item-total correlations and inter-item correlations. As proposed by Nunnally and Bernstein (1994), Cronbach's alpha coefficients between 0.70 - 0.90 were used as a measure of adequate internal consistency. Items that had an item-total correlation less than .30 were considered to discriminate poorly and were closely scrutinized. Factor analysis was used to establish construct validity of the HISB instrument. To model error variance, principal axis analysis was used to extract pertinent factors (Gorsuch, 2003). Correlation among extracted factors was expected, and therefore oblique rotation was employed. To determine which factors to retain, Kaiser criterion was used. Pertinent factors were identified when item loading coefficients were $\geq$ 0.30. The extraction criterion minimum eigenvalue was set at 1 (Kaiser, 1960).

Diabetes Self-Efficacy

Diabetes self-efficacy was measured with the Stanford Self-efficacy for Managing Diabetes Scale (Ware, Nelson, Sherbourne, & Stewart, 1992). The scale consisted of eight 10-point Likert-type items asking how confident the individual was in managing diabetes in the areas of diet, exercise, and general self-management behaviors (Appendix C-6). The scale ranges from 1 (not at all confident) to 10 (totally confident). A higher score indicates a higher level of self-efficacy. Internal consistency has been reported at 0.828 (Lorig, Ritter, Villa, & Armas, 2009).

Diabetes Self-Care Activities

Diabetes SCA were assessed with the 11-item Summary of Diabetes Self-Care

Activities (SDSCA) scale (Toobert et al., 2000). The SDSCA scale measures frequency of diabetes self-care in the past 7 days for five aspects of the diabetes regimen: two items for general diet (followed healthful diet), two items for specific diet (ate fruits/low fat diet), two items for foot care, two items for blood-glucose testing, two items for exercise, and one item for cigarette smoking (Appendix C-4). Response options range from 0 to 7 to correspond to the number of days in a week. The average score across items for each subscale or, in the instance of cigarette smoking, score for one item represents the frequency of performing the self-care behavior in the past 7 days. Reliability and validity data were analyzed from 7 different studies using the SDSCA. The results of that analysis showed that the internal consistency of the four SDSCA subscales, assessed by the average inter-item correlations was acceptable (r = 0.20 to 0.76, mean = 0.47); 4-month test-retest reliability ranged from r = -0.05 to 0.78 (Toobert et al., 2000).

DATA ANALYSIS

Data were analyzed using IBM SPSS Statistics Version 25 (IBM, 2017). Prior to analysis, all data was checked for missing values and variables were re-coded and created, where necessary. In addition, the assumptions of each statistical method were appropriately checked prior to analysis. All data was checked for descriptive statistics, including distributions, normality (skewness & kurtosis), linearity and homoscedasticity.

Standard psychometric methods, including Cronbach's alpha to assess internal consistency, reliability and factor analysis to assess the scale structure (partial construct validity), was used to verify the psychometric properties of summary scales for each of the major measurement instruments. Prior to testing the theoretical model guided

analysis, univariate distributions were inspected to assess normality and identify outliers, skewness, or other abnormalities in distribution, and to determine appropriate summaries of location and spread and the need for transformation. Items with little variation, excessive numbers of missing responses, or descriptive redundancy were excluded, except for the description of the sample and selected bivariate analyses. Attention was paid to multicollinearity among independent variables, and redundant items were eliminated from further multivariate analysis, based on theoretical and clinical considerations.

Research Question 1

What are the magnitude and direction of the relationships among personal characteristics (age, gender, language, acculturation, income, employment, housing type, education attainment, marital status, years with T2DM & insurance type) and health literacy among underserved patients with T2DM?

Bivariate correlations, including Pearson product moment correlation coefficients (for interval level data) and Phi correlation (for dichotomous data) were used to assess the relationships among personal characteristics (age, gender, language, acculturation, income, employment, housing type, education attainment, marital status, years with T2DM & insurance type) and the two health literacy instruments. Prior to the data analyses, data were analyzed to ensure the following assumptions were met: 1) normal distribution of the variables; 2) homoscedasticity was present; and 3) evidence of a linear relationship among the variables (Munro, 2005). Health literacy (NVS and DM-

REALM), age, acculturation level and years with T2DM are interval level measurements. Gender, language, employment and marital status are categorical variables that were dichotomized for this analysis. Categorical variables included income, housing type, education attainment, and insurance type.

Research Question 2

What are the magnitude and direction of the relationships among health literacy, diabetes knowledge, health information-seeking behaviors, diabetes self-efficacy, and diabetes SCA among underserved patients with T2DM?

Bivariate correlations (Pearson product moment correlation coefficients) were used to assess the relationships among the major variables of interest – diabetes SCA, functional health literacy, oral health literacy, diabetes knowledge, health information-seeking behaviors, and diabetes self-efficacy. Prior to the data analyses, data were analyzed to ensure the following assumptions were met: (1) normal distribution of the variables; (2) homoscedasticity was present; and (3) evidence of a linear relationship among the variables (Munro, 2005).

Research Question 3

Are there differences among diabetes knowledge, health information-seeking behaviors, diabetes self-efficacy or diabetes SCA between those with limited health literacy and those with adequate health literacy?

To identify statistical difference in mean counts of diabetes knowledge, health

information-seeking behaviors, diabetes self-efficacy, and diabetes SCA by level of health literacy, independent samples *t*-tests were conducted. Normal distribution of the dependent variables and homogeneity of variance were evaluated in the *t*-test.

Research Question 4

What are the significant predictors of the level of health literacy among underserved patients with T2DM?

Multiple linear regressions were calculated to predict the level of both functional health literacy (NVS) and oral health literacy based on personal characteristics. Prior to data analysis, assumptions including normality, independence, homoscedasticity and linearity were verified.

Research Question 5

What are the significant predictors of diabetes SCA among underserved patients with T2DM?

To determine the significant predictive variables of diabetes SCA, hierarchical multiple regression tests were employed. The order of variables entered into the model were based on theoretical considerations. Health behavior information and health behavior motivation variables were placed in the first block, and health behavioral skills were placed in the second block. The primary purpose of entering the variables this way is to evaluate the effect of type or category of variables, health behavior information, health behavior motivation, and health behavior skills in this study on the dependent

variable, diabetes SCA (Keith, 2006). Simultaneous entry of predictors within each block estimates the general coefficients of each variable. Two separate regression analyses were used for this question – the first incorporated functional health literacy as a potential predictor variable and the second incorporated oral health literacy as a significant predictor variable.

Research Question 6

Do health information-seeking behaviors and/or diabetes self-efficacy mediate the effects of health literacy on diabetes SCA among underserved patients with T2DM?

a. *Do health information-seeking behaviors mediate the effects of health literacy on diabetes SCA among low-income patients with T2DM?*
b. *Does diabetes self-efficacy mediate the effects of health literacy on SCA among low-income with T2DM?*

In order to examine the mediation effect of both health information-seeking behaviors and diabetes self-efficacy on the relationship between health literacy and diabetes SCA, two separate regression-based mediation analyses were conducted.

To test the mediation effect, the following three regression equations were conducted (Baron & Kenny, 1986).

- *First equation*: Regressing the mediator (health information-seeking behaviors or diabetes self-efficacy) on the independent variable (HL).
- *Second equation*: Regressing the dependent variable (diabetes SCA) on the independent variable (HL).

- *Third equation*: Regressing the dependent variable (diabetes SCA) on both independent variable (HL) and on the mediator (health information-seeking behaviors or self-efficacy).

A mediator is a variable that identifies the relationship between an independent variable and a dependent variable (Baron & Kenny, 1986). In order to establish a mediation effect, Baron & Kenny have outlined the following four conditions: (1) the independent variable (HL) significantly predicts the mediator (health information-seeking behaviors or diabetes self-efficacy) in the first equation; (2) the independent variable (HL) significantly predicts the dependent variable (diabetes SCA) in the second equation; (3) the mediator (health information-seeking behaviors or diabetes self-efficacy) significantly predicts the dependent variable (diabetes SCA) in the third equation; and lastly, (4) the effect of the independent variable (HL) on the dependent variable (diabetes SCA) must be less in the third equation than in the second. If the independent variable (HL) has no effect on the dependent variable (diabetes SCA) when the mediator is controlled, perfect mediation effect occurs.

SUMMARY

The purpose of this chapter was to describe the methods that were used for this correlational, descriptive, cross-sectional study using secondary analysis. A thorough description of the population, setting and sampling procedures were reviewed, as well as

a description of each instrument used in the study. Finally, six research questions were proposed, as well as the plan for data analysis to answer each question.

Chapter Four: Results

The purpose of this chapter is to present the results of the data analysis from this dissertation study. Data were collected from participants using a survey (as described in Chapter 3) and were entered into SPSS 25.0 (IBM, 2017). A thorough description of sample characteristics, descriptive statistics for each variable, psychometric properties of pertinent instruments and the results of the analysis for each research question, including univariate and multivariate analyses will be presented. Variable names, variable typology, categorical responses and number of participants that provided information regarding each variable are presented in Table 4.

DESCRIPTIVE STATISTICS OF THE SAMPLE & INSTRUMENTS

Descriptive statistics including the means, ranges, frequencies, standard deviations and percentages were used for analysis of the data. Demographic characteristics included age, gender, language, acculturation, income, employment, type of housing, education attainment, marital status, years with T2DM, and type of insurance. Major variables included health literacy (functional and oral health literacy), diabetes knowledge, health information-seeking behaviors, diabetes self-efficacy and diabetes SCA.

Demographic Characteristics of Participants

A total of 388 participants from six different clinics within one FQHC in an urban county of central Texas participated in this study. The six clinics were located in geographically diverse areas across the county. To qualify for this study, participants had

to be enrolled patients of the health center, diagnosed with Type 2 Diabetes, aged 18 or over and expressed willingness to participate in the study.

Table 4. *Description of variables & instruments*

Variable Name	Type of Variable	Options	Participants (*n*)
Demographics			
Location	Categorical	Central North Clinic East Clinic Southeast Clinic Far North Clinic Far Northeast Clinic South Clinic	388
Age	Interval	Year of birth	382
Gender	Dichotomous	Female Male	388
Language	Dichotomous	Spanish English	388
Acculturation	Interval	Likert Scale	388
Income	Categorical	< $10,000 per year $10,001 – $15,000 $15,001 – $20,000 $20,001 – $40,000 $40,001 – $60,000 > $60,000	367
Employment	Categorical	Employed Unemployed Retired Disabled Other	379
Housing Type	Categorical	Own Living with Relative/Friend Rent Public housing Other	381
Education Attainment*	Categorical	Did not graduate HS HS diploma Some college College Grad Graduate Degree Other	182*
Marital Status	Dichotomous	Living with partner Living without partner	381
Years with T2DM	Interval	Year of diagnosis	382
Insurance Type	Categorical	Medicaid Medicare Private MAP Other	388
Instruments			
Newest Vital Sign	Interval	Score	388
DM-REALM	Interval	Score	388
Diabetes Knowledge	Interval	Score	378
Health Info Seeking (5)	Interval	Score	381
Diabetes Self Efficacy	Interval	Score	382
Diabetes Self-Care Activities	Interval	Score	364

**Education attainment was missing from 206 printed surveys and collected from remaining 182 participants.*

Complete demographic data for participants are summarized and presented in Table 5. Of the 388 participants, most were recruited from the North Clinic with 150 participants (38.7%), followed closely by the South East Clinic with 113 participants (29.1%), the South Clinic with 58 participants (14.9%) and finally, the East Clinic with 51 participants (13.1%). As expected, fewer participants were recruited from smaller clinics in more rural areas; the Far North Clinic had 11 participants (2.8%) and the Far Northeast Clinic had 5 participants (1.3%). Overall, there was sufficient geographic diversity of participants across the county.

The survey was available in both English and Spanish. Approximately 32.7% of participants chose to complete the survey in Spanish. Acculturation, overall, was moderate among participants with an average of 12.71 (*SD* = 6.8). The majority of participants were female (64.7%) and the mean age was 53.07 years (*SD* = 10.33) with a range of 23 – 81 years. Participants reported living with Type 2 Diabetes for an average of 9.38 years (*SD* = 8.43) with a range of 0 – 49 years. Approximately 42% of participants reported that they had not yet completed high school, 22.5% had received a high school diploma and 26.3% of participants reported attending either some college, graduating from college or having received a graduate degree. Regarding marital status, 34.9% of participants were married and an additional 5.2% reported being partnered. Single participants accounted for 32.5% of the sample, 7.6% reported being widowed and 19.7% were divorced. For data analysis purposes, marital status was dichotomized into partnered (married or partnered) or un-partnered (single, widowed, or divorced).

Over half of the participants (58.3%) reported an annual income of less than $10,000 per year. Approximately 29% of participants reported an annual income between $10,000 and $20,000, while only 12% of participants reported earning more than $20,000 a year. Most participants were either unemployed (35.4%), disabled (28%), or retired (7.9%). For data analysis purposes and reflecting the income standard for poverty prevalent in the literature, income was dichotomized into either less than or equal to $20,000 or greater than $20,000 annually. Employed participants accounted for 22.7% of participants; 9.5% working full-time and 13.2% reported working part-time. Approximately 28% of participants reported that they rely on disability benefits for income. The majority of participants were living in non-permanent housing as 40.7% were renting their residence, 7.9% were in public housing and 24.4% reported living with either friends or relatives. Approximately 19% of participants owned their residence. In regards to health insurance coverage, the vast majority of participants (45%) received health benefits through the Medical Access Program (MAP), a county-tax funded program for low-income persons who do not qualify for either Medicaid or Medicare and are unable to afford private health insurance. Additionally, 14.2% of participants were enrolled in Medicaid, while 19.8% of participants received Medicare benefits. The FQHC offered a sliding fee scale program to patients who were ineligible for any other assistance program and 14.4% of participants reported using this benefit.

Table 5. *Demographic characteristics of study participants* (*n* = 388)

		n (%)	Mean (*SD*)	Range
Age			53.07 (10.33)	23 - 81
Gender	Female	247 (64.7)		
	Male	135 (35.3)		
Language	Spanish	127 (32.7)		
	English	261 (67.3)		
Acculturation			12.71 (6.8)	0 – 20
Location	Central North Clinic	150 (38.7)		
	East Clinic	51 (13.1)		
	Southeast Clinic	113 (29.1)		
	Far North Clinic	11 (2.8)		
	Far Northeast Clinic	5 (1.3)		
	South Clinic	58 (14.9)		
Annual income	≤ $10,000	214 (58.3)		
	$10,001 – $15,000	66 (18)		
	$15,001 – $20,000	42 (11.4)		
	$20,001 – $40,000	37 (10.1)		
	$40,001 – $60,000	6 (1.6)		
	> $60,000	2 (0.5)		
Employment	Employed	86 (22.2)		
	Unemployed	134 (35.4)		
	Disabled	106 (28)		
	Retired/Other	53 (14)		
Housing Type	Own	72 (18.9)		
	Living with relatives or friends	93 (24.4)		
	Rent	155 (40.7)		
	Public housing	30 (7.9)		
	Other	31 (8.1)		
Education	Did not graduate HS	76 (41.8)		
	HS diploma	41 (22.5)		
	Some college	33 (18.1)		
	College grad	9 (4.9)		
	Graduate degree	6 (3.3)		
	Other	17 (9.3)		
Marital status	Single	124 (32.5)		
	Married	133 (34.9)		
	Widowed	29 (7.6)		
	Divorced	75 (19.7)		
	Partnered	20 (5.2)		
Years with T2DM			9.38 (8.43)	0 – 49
Insurance	Medicaid	55 (14.2)		
	Medicare	77 (19.8)		
	Medical Access Program (MAP)*	175 (45.1)		
	Sliding Scale Payment	56 (14.4)		
	Private	20 (5.2)		
	Other	4 (1)		

**MAP: Medical Access Program (MAP) is for low-income persons or families without other healthcare coverage such as Medicaid, Medicare, or private insurance living in Travis County, TX.*

Descriptive Results of Instruments

The major variables of this study included health literacy (functional health literacy and oral health literacy), diabetes knowledge, health information-seeking behaviors, diabetes self-efficacy, and diabetes SCA. The instruments used to measure each variable, as well as the results from each instrument are listed in Table 6 below. Descriptive statistics, including information pertaining to the reliability of each instrument (range, mean, standard deviation, skewness, kurtosis, Shapiro-Wilk, significance, and Cronbach's alpha) are outlined in the same table. As proposed by Nunnally and Bernstein (1994), Cronbach's alpha coefficients between 0.70 - 0.90 were used as a measure of adequate internal consistency. Items that had an item-total correlation less than .30 were considered to discriminate poorly and were closely scrutinized.

Health literacy was measured using the summed score of two instruments: the Newest Vital Sign (NVS) and the DM-REALM. The NVS score represents the participants' functional health literacy as it encompasses prose, quantitative, and document literacy (Weiss et al., 2005). The score from the DM-REALM represents diabetes-specific oral health literacy. For clarity in data reporting, the results from the NVS will be reported as "functional health literacy" and the DM-REALM will be reported as "oral health literacy". Diabetes knowledge was measured with the Michigan Diabetes Knowledge Test (DKT). Health information-seeking behaviors were measured using a subscale of Porter Novelli's Health Styles consumer opinion survey, referred to as the Health Information Seeking Behaviors (HISB) survey. Diabetes self-efficacy was

measured using the Stanford Self-efficacy for Managing Diabetes scale. Finally, diabetes SCA were measured with the Summary of Diabetes Self Care Activities scale (SDSCA).

Table 6. *Descriptive results of instruments used in this study*

Instrument	Number of Items	Possible Range	Score Range	Mean (*SD*)	Skewness (SE)	Kurtosis (SE)	Shapiro-Wilk	Cronbach's Alpha	Standard Chron Alpha	Item-total *r*
NVS	6	0 – 6	0 – 6	1.77 (1.742)	.945 (.124)	-.122 (.247)	.000	.771	.775	.395 -. 642
DM-REALM	82	0 – 82	0 – 82	42.37 (24.51)	-.240 (.124)	-.915 (.247)	.000	.986	.986	.490 - .877
DKT	14	0 – 14	0 – 12	5.65 (2.36)	.010 (.129)	-.521 (.258)	.000	-	-	-
HISB	7	7 – 35	17 – 35	27.06 (3.71)	-.488 (.129)	1.201 (.258)	.000	.616	.657	.210 - .498
DSE	8	8 – 80	8 – 80	55.32 (16.08)	-.565 (.129)	.190 (.258)	.000	.832	.836	.446 - .644
SDSCA	10	0 – 70	0 – 70	41.45 (13.76)	-.267 (.129)	-.308 (.258)	.013	.703	.704	.107 - 518

NVS=Newest Vital Sign; DM-REALM=Diabetes Mellitus-Rapid Estimate of Adult Literacy in Medicine; DKT=Diabetes Knowledge Test; HISB=Health Information Seeking Behavior; DSE=Diabetes Self Efficacy; SDSCA=Summary of Diabetes Self Care Activities

Functional Health Literacy. The NVS exhibited adequate internal consistency (Cronbach's alpha coefficient = .771). The skewness index was .945, which indicates a markedly positive skew of the data. The kurtosis index was -.122 which indicates a distribution that is only slightly more platykurtic than leptokurtic. Although the Shapiro-Wilk test was significant for this measure, the absolute values of skewness and kurtosis were both less than 1, indicating a normal distribution of the scores (Hair, Anderson, Tatham & Black, 1998).

However, when functional health literacy scores were analyzed as the dependent variable (i.e. in the linear regression model to predict functional health literacy), log transformation was required to normalize the distribution. To do this, the log of each individual observation was calculated and used for the regression analysis.

Oral Health Literacy. The DM-REALM also exhibited adequate internal consistency (Cronbach's alpha coefficient = .986). The skewness index was -.240, which indicates a slight negative skew of the data. The kurtosis index was -.915 which indicates a distribution that is only slightly more platykurtic than leptokurtic. Although the Shapiro-Wilk test was significant for this measure, the absolute values of skewness and kurtosis were both less than 1, indicating a normal distribution of the scores (Hair et al., 1998).

Health Information-Seeking Behaviors. Analysis of the 7-item Health Information Seeking Behavior scale revealed inadequate internal consistency (Cronbach's alpha coefficient = .616). Item analysis revealed that items 1 and 3 produced item-total correlations less than .30. Therefore, items 1 and 3 were removed and item

analysis was repeated. The new 5-item HISB scale produced an improved and adequate Cronbach's alpha coefficient of .706. Descriptive statistics, including information pertaining to the reliability of the new 5-item HISB instrument (range, mean, standard deviation, skewness, kurtosis, Shapiro-Wilk, significance, and Chronbach's alpha), as compared with the original 7-item HISB are highlighted in Table 7. Additionally, principal factor analysis for the original 7-item scale revealed one factor solution (Eigenvalue of 2.449 and explained 34.99% of the total variance). However, there are two items that have low item to total correlation as well as low factor loading, indicating potential measurement error. The revised 5-item scale (without those two items) produced a latent factor with slightly lower Eigen value but significantly higher explanatory power (Eigenvalue of 2.392 and explained 47.83% total variance) (Table 7). Therefore, the revised 5-item HISB scale was used for this dissertation study.

Items 1 *("I don't have time to bother learning a lot of health information."*) and 3 *("I don't pay attention to health information unless it's about a problem I have.*") are both negatively anchored items, while the five remaining items are all positively anchored (e.g. "*I make a point to read/watch stories about health*"). Previous research has shown that instruments with mixed response anchors contribute to increasing error variance, particularly among ethnic minority populations (Kim et al., 2015).

Table 7. *Health Information-Seeking Behaviors (HISB) – Revision of Scale*

Items	Before Items 1 & 3 Removed	After Items 1 & 3 Removed
	Factor Loading	Factor Loading
1. I don't have time to bother learning a lot of health information.	-.173	---
2. I make a point to read/watch stories about health.	.552	.542
3. I don't pay attention to health information unless it's about a problem I have.	-.260	---
4. When sick, I try to get information about my disease.	.615	.636
5. I like to get health information from a variety of sources.	.746	.745
6. When I take medicine, I try to get as much information about benefits and side effects.	.789	.789
7. Before making a decision about my health, I find out everything I can about this issue.	.700	.719
Eigenvalue	2.449	2.392
Variance (%)	34.991	47.834
Cronbach's alpha	.616	.706
Standardized Cronbach's alpha	.657	.722
Item-total r	.210 - .498	.359 - .559

Table 8. *Descriptive results of HISB-7 and HISB-5*

Instrument	Number of Items	Possible Range	Score Range	Mean (SD)	Skewness (SE)	Kurtosis (SE)	Shapiro-Wilk	Cronbach's Alpha	Standard Chron Alpha	Item-total *r*
HISB-7	7	7 – 35	17 – 35	27.06 (3.71)	-.488 (.129)	1.201 (.258)	.000	.616	.657	.210 - .498
HISB-5	5	5 - 25	9 – 25	20.15 (2.87)	-.612 (.125)	1.313 (.2490	.942	.706	.722	.180 - .571

Diabetes Self-Efficacy. The Stanford Self-efficacy for Managing Diabetes scale exhibited adequate internal consistency (Cronbach's alpha coefficient = .832). The skewness index was -.565, which indicates a moderately negative skew of the data. The kurtosis index was .190 which indicates a distribution that is only slightly more platykurtic than leptokurtic. Although the Shapiro-Wilk test was significant for this measure, the absolute values of skewness and kurtosis were both less than 1, indicating a normal distribution of the scores (Hair et al., 1998).

Diabetes Self-Care Activities. The Summary of Diabetes Self Care Activities scale exhibited adequate internal consistency (Cronbach's alpha coefficient = .703). The skewness index was -.267, which indicates a slightly negative skew of the data. The kurtosis index was -.308 which indicates a distribution that is only slightly more platykurtic than leptokurtic. Although the Shapiro-Wilk test was significant for this measure, the absolute values of skewness and kurtosis were both less than 1, indicating a normal distribution of the scores (Hair et al., 1998).

DESCRIPTIVE STATISTICS FOR STUDY VARIABLES

Health Literacy. Two instruments were used to measure health literacy – the NVS and the DM-REALM. The NVS (used to measure functional health literacy) was the first instrument presented in the survey and was completed by all study participants (*n* = 388). The possible scores on the NVS range from 0 – 6. Participant scores also ranged from 0 – 6. A score of 0 – 1 indicates a "high likelihood of limited health literacy", scores from 2 – 3 indicate a "possible likelihood of limited health literacy" and scores of 4 – 6 indicate an "adequate level of health literacy". The average score on the Newest Vital

Sign was 1.73 (*SD* 1.75). For reporting purposes and following the instructions provided by the original instrument author, the NVS scores were often dichotomized into two groups – those with "adequate health literacy" (score of 4 – 6) and those with "limited health literacy" (score of 0 – 3). Approximately 82% of study participants exhibited limited health literacy (57.2% with high likelihood of limited health literacy and 24.5% with possibly limited health literacy), and 18.3% exhibited adequate health literacy.

Although the summed score of the NVS was often used for data analysis, there were important discrepancies among the questions answered correctly by participants. Questions 1 – 4 on the NVS primarily address numeracy skills and questions 5 and 6 primarily address prose and document literacy. Item 1 requires multiplication skills as the participant must recognize that there are 4 servings in the container of ice cream and then must multiply that by the number of calories per serving (250) to produce a correct answer of 1000 calories. Less than one quarter of participants answered this question correctly.

Participants performed slightly better (28% answered correctly) on item 2 which requires the participant to find carbohydrate content on the label, recognize there are 30g of carbohydrates in each serving and divide their snack allowance of 60g of carbohydrates by this serving size and produce an answer of "one cup". Calculation of carbohydrates is an essential element of diabetes diet management (NIDDK, n.d.).

Less than 20% of participants were able to answer items 3 and 4 correctly. Item 3 tests the participant's ability to subtract and item 4 assesses their ability to calculate percentage. Notably, over 60% of participants answered item 5 correctly which requires

the participant to find the ingredients on the label and recognize that peanuts are on the list (an allergen) – "*Is it safe for you to eat this ice cream?*" And although many answered item 5 correctly with an answer of "*no*" – that this ice cream is not safe to eat, only 34% of participants were able to correctly identify the reason for this decision (item 6 – "*Why not?*"). Anecdotally, among participants that answered item 5 correctly and item 6 wrong, the most common incorrect answer was "*I have diabetes and can't (or am not supposed to) eat ice cream*". For each item, it is essential for the participant to be able to locate the information on the label to answer the question or have some familiarity with a nutrition label. Further details regarding participant performance on the Newest Vital Sign are presented in Table 9.

Table 9. *Functional Health Literacy assessment results* (*n* = 388)

Functional Health Literacy: Newest Vital Sign		Mean + SD *n* (%) Correct
	Average	1.73 (1.75)
	Range	0 - 6
	Median	1.00
Scores of NVS – Categories of health literacy		
	Adequate health literacy (4-6)	71 (18.3)
	Possible limited health literacy (2-3)	95 (24.5)
	High likelihood of limited health literacy (0-1)	222 (57.2)
Item 1	If you eat the entire container, how many calories will you eat?	89 (22.9)
Item 2	If you are allowed to eat 60g of carbohydrates as a snack, how much ice cream could you have?	110 (28.4)
Item 3	Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42g of saturated fat each day, which includes 1 serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would be consuming each day?	56 (14.4)
Item 4	If you usually eat 2500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?	52 (13.4)
Item 5	"Pretend that you allergic to the following substances: penicillin, peanuts, latex gloves and bee stings." Is it safe for you to eat this ice cream?	241 (62.1)
Item 6	Why not? (Ask only if the participant responds "no" to question 5.)	132 (34)

The DM-REALM (to measure oral health literacy) was the second instrument presented to participants and administered by the RA in either English or Spanish (based on the preference of the participant). This tool is comprised of 82 items that assesses an individual's ability to pronounce words commonly used in diabetes self-management. Each item was either pronounced correctly (score of 1) or incorrectly (score of zero). Possible scores ranged from 0 – 82. Participant scores also ranged from 0 - 82. Using the original REALM instrument score ranges as a guide (Davis et al. 1993), scores were dichotomized into two groups: scores ranging from 0 to 75 indicated inadequate oral

health literacy and scores above 76 indicated adequate oral health literacy. Among study participants, 89.6% exhibited limited oral health literacy and 10.3% performed adequately on the instrument. Table 10 presents more detailed information about participant performance on the DM-REALM.

Table 10. *Oral health literacy (DM-REALM) assessment results* (*n = 388*)

DM-REALM	Mean ± *SD* / *N* (%) Correct
Average	42.37 ± 24.51
Range	0-82
Median	44
Mean % of correct	63.0
English version	62.1
Spanish version	63.8

1st column		*N* (%) Correct	2nd column		*N* (%) Correct	3rd column		*N* (%) Correct
Item 1	*Pill*	254 (65.3)	Item 1	*Dizzy*	278 (71.5)	Item 1	*Glaucoma*	221 (56.8)
Item 2	*Eye*	306 (78.7)	Item 2	*Fatigue*	257 (66.1)	Item 2	*Circulation*	253 (65.0)
Item 3	*Fat*	276 (71.0)	Item 3	*Exchange*	277 (71.2)	Item 3	*Nephropathy*	135 (34.7)
Item 4	*Brain*	303 (77.9)	Item 4	*Protein*	239 (61.4)	Item 4	*Hypoglycemia*	164 (42.2)
Item 5	*Sugar*	318 (81.7)	Item 5	*Injection*	253 (65.0)	Item 5	*Endocrinologist*	136 (35.0)
Item 6	*Fiber*	260 (66.8)	Item 6	*Exercise*	235 (60.4)	Item 6	*Ophthalmologist*	153 (39.3)
Item 7	*Meal*	225 (57.8)	Item 7	*Diabetes*	204 (52.4)	Item 7	*Triglyceride*	159 (40.9)
Item 8	*Meat*	274 (70.4)	Item 8	*Fluid*	277 (71.2)	Item 8	*Necrosis*	145 (37.3)
Item 9	*Fruit*	273 (70.4)	Item 9	*Portion*	265 (68.1)	Item 9	*Cardiovascular disease*	174 (44.7)
Item 10	*Rice*	265 (68.1)	Item 10	*Serving*	246 (63.2)	Item 10	*Hyperglycemia*	180 (46.3)
Item 11	*Bread*	265 (68.1)	Item 11	*Obesity*	238 (61.2)	Item 11	*Dialysis*	193 (49.6)
Item 12	*Heart*	263 (67.6)	Item 12	*Dosage*	257 (66.1)	Item 12	*Ketone*	191 (49.1)
Item 13	*Blood*	306 (78.7)	Item 13	*Calorie*	269 (69.2)	Item 13	*Prescription*	208 (53.5)
Item 14	*Needle*	285 (73.3)	Item 14	*Infection*	268 (68.9)	Item 14	*Amputation*	192 (46.2)
Item 15	*Hospital*	285 (73.3)	Item 15	*Stroke*	291 (74.8)	Item 15	*Pharmacist*	189 (48.6)
Item 16	*Vision*	293 (75.3)	Item 16	*Fasting*	280 (72.0)	Item 16	*Medication*	190 (48.8)
Item 17	*Snack*	298 (76.6)	Item 17	*Glucose*	266 (68.4)	Item 17	*Lancet*	172 (44.2)
Item 18	*Strip*	303 (77.9)	Item 18	*Shaking*	265 (68.1)	Item 18	*Pancreas*	155 (39.8)
Item 19	*Insulin*	286 (73.5)	Item 19	*Nutrition*	252 (64.8)	Item 19	*Glucometer*	184 (47.3)
Item 20	*Alcohol*	284 (73.0)	Item 20	*Vegetable*	292 (75.1)	Item 20	*Cataract*	183 (47.0)
Item 21	*Foot*	274 (70.4)	Item 21	*Emergency room*	255 (65.6)	Item 21	*Carbohydrate*	206 (53.0)
Item 22	*Shock*	259 (66.6)	Item 22	*Swelling*	237 (60.9)	Item 22	*Monitoring*	199 (51.2)
Item 23	*Diet*	294 (75.6)	Item 23	*Sweating*	292 (75.1)	Item 23	*Physical activity*	201 (51.7)
Item 24	*Lab*	272 (69.9)	Item 24	*Appointment*	268 (68.9)	Item 24	*Cholesterol*	204 (52.4)
Item 25	*Family history*	281 (72.2)	Item 25	*Blood pressure*	252 (64.8)	Item 25	*Hemoglobin A1C*	172 (44.2)
Item 26	*Weight*	255 (65.6)	Item 26	*Refill*	276 (71.0)			
Item 27	*Nerve*	283 (72.8)	Item 27	*Redness*	275 (70.7)			
Item 28	*Cut*	285 (73.3)	Item 28	*Kidney*	268 (68.9)			
Item 29	*Sore*	276 (71.0)						

Diabetes Knowledge. Diabetes knowledge was assessed using the Diabetes Knowledge Test (DKT). The possible scores on this 14-question assessment ranged from 0 – 14, with a higher score indicating a higher level of diabetes knowledge. Answers are either correct or incorrect. Participant scores ranged from 0 – 12. The average score on the DKT was 5.65 (*SD* 2.364).

Health Information-Seeking Behaviors. Health information-seeking behaviors were measured using the modified 5-item HISB instrument. The possible score range of the original 7-item instrument was 7 – 35. Scores of participants ranged from 17 – 35. The average score was 27.06 (*SD* 3.713). After the instrument was modified to include only the five positively anchored statements and eliminated the two negatively anchored statements, the new possible scores ranged from 5 – 25. Scores of participants ranged from 9 – 25. The average score was 20.15 (*SD* 2.87). Further details about this tool are provided in Table 11.

Table 11. *Health information-seeking behavior assessment results* (*n* = 382)

Health Information Seeking Behavior: HISB – Modified 5 Item		Mean ± SD *n* (%) Correct
	Average	20.15 (2.87)
	Range	5 – 25
	Median	19.88
Scores of HISB		
Item 2	I make a point to read/watch stories about health.	3.70 (1.07)
Item 4	When sick, I try to get information about my disease.	4.13 (0.79)
Item 5	I like to get health information from a variety of sources.	3.97 (0.87)
Item 6	When I take medicine, I try to get as much information about benefits and side effects.	4.15 (0.78)
Item 7	Before making a decision about my health, I find out everything I can about this issue.	4.17 (0.72)

Diabetes Self-Efficacy. Self-efficacy among participants related to their confidence in managing their diabetes was measured with the Stanford Self Efficacy for Managing Diabetes Scale. This 8-item scale had a score range of 8 – 80, with higher scores indicating a higher level of diabetes self-efficacy. The average score among participants in this study was 55.32 (*SD* 16.078).

Diabetes Self-Care Activities. The Summary of Diabetes Self-Care Activities was used to measure participant's self-report of SCA over the last seven days. The original SDSCA instrument consists of 11 items – 4 items related to diet, 2 items related to exercise, 2 items related to blood glucose testing, 2 related to foot care, and 1 item related to smoking. The first 10 questions are all worded similarly. For example, "On how many of the last SEVEN DAYS did you check your feet?". However, the eleventh question – "Have you smoked a cigarette – even one puff – during the past SEVEN DAYS?" is a yes or no question and requires the participant to answer a second question if answered affirmatively – "How many cigarettes did you smoke on an average day?". Among the sample of 388 participants, 55 (14%) answered affirmatively that they had smoked in the past week. However, many failed to answer how many cigarettes they smoked per day. Therefore, this question could not reasonably be included in statistical analyses. This same issue has been reported in several studies authored by the instrument's developer (Glasgow et al., 1992; Glasgow et al., 1999; Glasgow & Toobert, 2000) and therefore, smoking was not used as part of the score. The 10-item scale had a score range of 0 – 70, with higher scores indicating higher frequency of diabetes SCA in the previous week. The average score was 41.45 (*SD* 13.756). The four sub-scale means

were used only for an ad-hoc analysis of the relationships between the main theoretical constructs and diabetes SCA (Table 14).

FINDINGS FOR RESEARCH QUESTIONS

All data were cleaned and validated by cross checking each data point against minimum and maximum possible data points for each variable. No outliers were identified during data cleaning. All variables were assessed for normality. The level of statistical significance for this study was set at $p < .05$. Missing data was addressed by listwise deletion as the portion of missing data was minimal (less than 10%). Research questions were addressed using descriptive statistics, bivariate correlations, chi-square, regression analysis and mediation analysis.

Research Question 1

What are the magnitude and direction of the relationships among personal characteristics (age, gender, language, acculturation, income, employment, housing type, education attainment, marital status, years with T2DM, & insurance type) and health literacy among underserved patients with T2DM?

Bivariate correlations, including Pearson product moment correlation coefficients (for interval level data) and Phi correlation (for dichotomous data) were used to assess the relationships among personal characteristics and the two health literacy instruments. Health literacy (NVS and DM-REALM), age, acculturation level and years with T2DM are interval level measurements. Gender, language, employment and marital status are categorical variables that were dichotomized for this analysis. Categorical variables

included income, housing type, education attainment, and insurance type. The results of these correlations are presented in Table 12.

Functional health literacy (Newest Vital Sign). Functional health literacy (as measured by the NVS) exhibited a weak significant relationship with age, $r = -.173$, $p < .01$; gender, $r = -.170$, $p < .01$; language, $r = .222$, $p < .01$; acculturation, $r = .287$, $p < .01$; income, $r = .116$, $p < .05$; education, $r = .313$, $p < .01$; and marital status, $r = .126$, $p < .01$. Those with higher scores on the NVS were more likely to be younger, female, unmarried, English-speaking, more acculturated, and have higher income and completed more years of education. Functional health literacy was not significantly related to employment status, housing type, years with T2DM, or insurance.

Oral health literacy (DM-REALM). Oral health literacy (as measured by the DM-REALM) showed a weak significant relationship with gender, $r = -.101$, $p < .05$; employment status, $r = -.160$, $p < .01$; and insurance, $r = .138$, $p < .01$. Those with higher scores on the DM-REALM were more likely to be female, employed, and have private insurance. Oral health literacy was not significantly related to age, language, acculturation, income, housing type, education, marital status, and years with T2DM.

Age. Age showed a weak significant relationship with functional health literacy, $r = -.173$, $p < .01$; language, $r = .102$, $p < .05$; employment status, $r = .260$, $p < .01$; marital status, $r = .196$; years with T2DM, $r = .288$, $p < .01$; and insurance type, $r = -.355$, $p < .01$. As age increased, so too did the number of years with T2DM as well as the likelihood that the participant was married or employed. Age was inversely related to

functional health literacy. Age was not significantly related to any other personal characteristics.

Gender. Gender showed a weak significant correlation with functional health literacy, $r = -.170$, $p < .01$; oral health literacy, $r = -.101$, $p < .05$; type of housing, $r = .122$, $p < .05$; and years with T2DM, $r = .113$, $p < .05$. Male gender was associated with lower functional and oral health literacy, higher income, more years living with T2DM and more permanent housing. Gender was not significantly related to acculturation, income, employment status, education level, marital status, or insurance status.

Language. Language exhibited a strong significant correlation with acculturation, $r = .729$, $p < .01$ and weak significant correlations with functional health literacy, $r = .222$, $p < .01$; age, $r = .102$, $p < .05$; employment, $r = .275$, $p < .01$; marital status, $r = .289$, $p < .01$; and insurance, $r = -.481$, $p < .01$. English-speaking ability was associated with higher acculturation, higher functional health literacy, employment status, being single and publicly insured. Language was not significantly related to gender, income, housing type, education level, and years with T2DM.

Acculturation. As previously reported, acculturation exhibited a strong significant correlation with language, $r = .729$, $p < .01$, but it also exhibited weak significant correlations with functional health literacy, $r = .287$, $p < .01$; employment, $r = .281$, $p < .01$; housing type, $r = .127$, $p < .05$; education, $r = .292$, $p < .01$ and marital status, $r = .255$, $p < .01$. Participants with higher acculturation were more likely to speak English, have higher functional health literacy, be employed, have more secure housing have more

years of education and un-partnered. Acculturation was not significantly related to age, gender, income, years with T2DM, or type of insurance.

Income. Income exhibited a weak significant correlation with functional health literacy, $r = .116$, $p < .05$; type of housing, $r = -.131$, $p < .05$; education attainment, $r = .239$, $p < .01$; and marital status, $r = -.276$, $p < .01$ and years with T2DM, $r = .117$, $p < .05$. Participants that reported a higher annual income were more likely to have higher functional health literacy, have higher education attainment, more secure housing, and married. Income was not significantly related to age, language, acculturation, employment status or type of insurance.

Employment. Employment status showed a weak significant correlation with age, $r = .260$, $p < .01$; language, $r = .275$, $p < .01$; acculturation, $r = .281$, $p < .01$; marital status, $r = .123$, $p < .05$; years with T2DM, $r = .118$, $p < .05$; and type of insurance, $r = -.439$, $p < .01$. Participants that were employed were more likely to be older, speak English, more acculturated, un-partnered, have lived with diabetes longer and be publicly insured. Employment was not significantly related to gender, income, type of housing, or education level.

Type of housing. Type of housing showed a weak significant correlation with gender, $r = .122$, $p < .05$; acculturation, $r = .127$, $p < .05$; and income, $r = -.131$, $p < .05$. Participants that had more secure housing were more likely to be male, more acculturated and report a lower annual income. Type of housing was not significantly related to any other personal characteristics.

Education attainment. Education attainment exhibited a weak significant correlation with functional health literacy, $r = .313$, $p < .01$, acculturation, $r = .292$, $p < .01$; and income, $r = .239$, $p < .01$. Study participants that reported more years of education were more likely to have higher functional health literacy, higher level of acculturation and earn a higher income. Education attainment was not significantly related to any other personal characteristics.

Marital status. Marital status showed a weak significant correlation to functional health literacy, $r = .126$, $p < .01$; age, $r = .196$, $p < .01$; language, $r = .289$, $p < .01$; acculturation, $r = .255$, $p < .01$; income, $r = -.276$, $p < .01$; employment, $r = .123$, $p < .05$; and insurance, $r = -.238$, $p < .01$. Being unmarried (un-partnered) was associated with a higher level of health literacy, English-speaking, higher level of acculturation, lower income and being publicly insured. Marital status was not significantly related to any other personal characteristics.

Years with T2DM. Number of years living with T2DM showed weak significant correlations with age, $r = .288$, $p < .01$; gender, $r = .113$, $p < .05$; income, $r = .117$, $p < .05$; employment status, $r = .118$, $p < .05$; and insurance, $r = -.103$, $p < .05$. Participants who have lived with diabetes longer were more likely to be older, male, employed and have public insurance. Years with T2DM were not significantly related to any other personal characteristics.

Type of Insurance. Insurance exhibited a weak significant correlation to oral health literacy, $r = .138$, $p < .01$; age, $r = -.355$, $p < .01$; language, $r = -.419$, $p < .01$; acculturation, $r = -.335$, $p < .01$; employment, $r = -.439$, $p < .01$; marital status, $r = -.238$,

$p < .01$; and years with T2DM, $r = -.103$, $p < .01$. Type of insurance was related to oral health literacy, age, language, acculturation, employment, marriage, and years with T2DM. Type of insurance was not significantly related to any other personal characteristics.

Table 12. *Bivariate correlations among study variables* (*n = 388*)

Variables	1	2	3	4	5	6	7	8	9	10	11	12	13
1. NVS	1												
2. DM-REALM	.025	1											
3. Age	-.173**	-.069	1										
4. Gender	-.170**	-.101*	.073	1									
5. Language	.222**	-.072	.102*	.049[a]	1								
6. Acculturation	.287**	-.060	.042	.039	.729**	1							
7. Income	.116*	.092	.052	.085	-.062	-.045	1						
8. Employment	.021	-.160**	.260**	-.067	.275**	.281**	-.071	1					
9. Housing Type	.032	-.028	-.074	.122*	.072	.127*	-.131*	.049	1				
10. Education	.313**	.085	-.057	.069	.140	.292**	.239**	-.071	.016	1			
11. Marital Status	.126**	-.063	.196**	.000[a]	.289**[a]	.255**	-.276**	.123*	.055	.033	1		
12. Years with T2DM	-.050	-.003	.288**	.113*	.070	.028	.117*	.118*	-.047	.079	.041	1	
13. Insurance	.025	.138**	-.355**	.014	-.419**	-.335**	.084	-.439**	-.040	.035	-.238**	-.103*	1

* $p < .05$, ** $p < .01$

An additional question was added to this analysis to address differences in personal characteristics between those with limited and those with adequate health literacy. To assess the differences between personal characteristics (age, gender, language, acculturation, income, employment, housing type, education, marital status and insurance) and health literacy (functional and oral health literacy), chi-square tests were employed after dichotomizing all variables. These results are presented in Table 13.

Functional Health Literacy. When functional health literacy was dichotomized into two groups – limited and adequate HL, significant differences in the groups emerged based on demographic characteristics. Language, $\chi^2 = 23.270$, $p < .001$; income, $\chi^2 = 23.203$, $p < .001$; education, $\chi^2 = 18.570$, $p < .001$; marital status, $\chi^2 = 4.710$, $p < .05$; and insurance, $\chi^2 = 6.930$, $p < .01$ were significantly different by functional health literacy status. Age, gender, acculturation, employment, and housing type did not significantly differ based on functional health literacy status.

Oral Health Literacy. When oral health literacy was dichotomized into two groups – limited and adequate HL, only one significant difference between the groups emerged based on demographic characteristics. Employment status, $\chi^2 = 3.862$, $p < .05$ differed significantly by oral health literacy status. No other demographic characteristics varied significantly based on oral health literacy status.

Table 13. *Personal characteristics by level of health literacy (n = 388)*

	Functional Health Literacy (NVS)		χ^2	Oral Health Literacy (DM-REALM)		χ^2
	Limited (score = 0 – 3) *n* = 317	Adequate (score = 4 – 6) *n* = 71		Limited (score = 0 – 75) *n* = 348	Adequate (score = 76 – 82) *n* = 40	
Age in years			3.596			0.169
23 – 64	268 (86.2%)	67 (94.4%)		300 (87.5%)	35 (89.7%)	
≥ 65	43 (13.8%)	4 (5.6%)		43 (12.5%)	4 (10.3%)	
Gender			3.807			0.968
Female	194 (62.4%)	53 (74.6%)		219 (63.8%)	28 (71.8%)	
Male	117 (37.6%)	18 (25.4%)		124 (36.2%)	11 (28.2%)	
Language			23.270***			0.104
English	196 (61.8%)	65 (91.5%)		235 (67.5%)	26 (65.0%)	
Spanish	121 (38.2%)	6 (8.5%)		113 (32.5%)	14 (35.0%)	
Acculturation			0.291			1.538
Less acculturated	7 (6.8%)	0 (0.0%)		122 (35.1%)	18 (45.0%)	
More acculturated	96 (93.2%)	4 (100.0%)		226 (64.9%)	22 (55.0%)	
Income			23.203***			0.656
Less than $20,000	132 (41.6%)	8 (11.3%)		290 (88.7%)	32 (84.2%)	
$20,001 - $60,000	185 (58.4%)	63 (88.7%)		37 (11.3%)	6 (15.8%)	
Employment			0.110			3.862*
Employed	70 (22.4%)	16 (24.2%)		72 (21.2%)	14 (35.0%)	
Other	243 (77.6%)	50 (75.8%)		267 (78.8%)	26 (65.0%)	
Housing type			1.317			.0378
Own	56 (17.8%)	16 (23.9%)		63 (18.5%)	9 (22.5%)	
Other	258 (82.2%)	51 (76.1%)		278 (81.5%)	31 (77.5%)	
Education			18.570***			0.238
High school/GED education or less	106 (71.6%)	11 (32.4%)		97 (65.1%)	20 (60.6%)	
At least some college	42 (28.4%)	23 (67.6%)		52 (34.9%)	13 (39.4%)	
Marital status			4.710*			1.003
Married/partnered	134 (42.7%)	19 (28.4%)		134 (39.3%)	19 (47.5%)	
Single/divorced/widowed	180 (57.3%)	48 (71.6%)		207 (60.7%)	21 (52.5%)	
Insurance			6.930**			0.000
Medical Access Program (MAP)	133 (42.0%)	42 (59.2%)		157 (45.1%)	18 (45.0%)	
Other	184 (58.0%)	29 (40.8%)		191 (54.9%)	22 (55.0%)	

* $p < .05$, ** $p < .01$, *** $p < .001$

Research Question 2

What are the magnitude and direction of the relationships among health literacy, diabetes knowledge, health information seeking, diabetes self-efficacy and diabetes SCA among underserved patients with T2DM?

Bivariate correlations (Pearson product moment correlation coefficients) were used to assess the relationships among the major variables of interest – diabetes SCA, functional health literacy, oral health literacy, diabetes knowledge, health information-seeking behaviors, and diabetes self-efficacy. The results of these correlations are presented in Table 14.

Self-care activities. Diabetes self-care activities showed a significant moderate correlation to diabetes self-efficacy, $r = .484$, $p < .01$ and a significant weak correlation to health information-seeking behaviors, $r = .256$, $p < .01$. Participants who reported more frequent diabetes care activities over the last seven days were more likely to report higher diabetes self-efficacy and more proactive health information-seeking behaviors. Diabetes SCA were not significantly related to health literacy (NVS or DM-REALM) or diabetes knowledge. However, when individual behaviors were extracted from the sum scale of SCA, diet showed a significant weak correlation to oral health literacy, $r = .127$, $p < .05$. No other individual diabetes SCA were correlated with oral or functional health literacy.

Functional health literacy (NVS). Functional health literacy (as measured by the NVS) exhibited a significant weak correlation to diabetes knowledge, $r = .388$, $p < .01$ and health information-seeking behaviors, $r = .106$, $p < .05$. Those with higher scores on the NVS were likely to have more knowledge about diabetes and show more proactive

health information-seeking behaviors. Functional health literacy was not significantly related to diabetes self-efficacy or diabetes SCA.

Oral health literacy (DM-REALM). Oral health literacy (as measured by the DM-REALM) exhibited a significant weak correlation to health information-seeking behaviors, $r = .123$, $p < .05$. Those with higher scores on the DM-REALM were more likely to report more proactive health information-seeking behaviors. Oral health literacy was not significantly correlated with diabetes knowledge, diabetes self-efficacy, or diabetes SCA.

Diabetes knowledge. Diabetes knowledge showed a significant weak correlation to functional health literacy (NVS), $r = .388$, $p < .01$ and health information-seeking behaviors, $r = .123$, $p < .05$. Participants with more knowledge about diabetes were more likely to have higher health literacy and report more proactive health information-seeking behaviors. Diabetes knowledge was not significantly related to the DM-REALM, diabetes self-efficacy, or diabetes self-care activities.

Health information-seeking behaviors. Health information-seeking behaviors exhibited a significant weak correlation with diabetes SCA, $r = .256$, $p < .01$, functional health literacy as measured by the NVS, $r = .106$, $p < .05$ and oral health literacy as measured by the DM-REALM, $r = .123$, $p < .05$, and diabetes knowledge, $r = .105$, $p < .01$. Those who more proactively sought out health information were more likely to report more frequent diabetes care activities over the last seven days, have higher health literacy (both the NVS and DM-REALM) and have more knowledge about diabetes

management. Health information-seeking behaviors were not significantly related to diabetes self-efficacy.

Diabetes self-efficacy. Diabetes self-efficacy showed a significant moderate relationship with diabetes self-care activities, $r = .484$, $p < .01$. Participants with a higher sense of self-efficacy related to managing their diabetes were more likely to report more frequent diabetes SCA. Diabetes self-efficacy was not significantly related to health literacy, diabetes knowledge, or health information-seeking behaviors.

Table 14. *Bivariate correlations among study variables* (*n* = 388)

Variables	1	2	3	4	5	6	7	8	9	10
1. SCA	1									
2. SCA: Diet	.715**	1								
3. SCA: Exercise	.556**	.209**	1							
4. SCA: Glucose check	.596**	.212**	.073	1						
5. SCA: Foot care	.630**	.236**	.235**	.167**	1					
6. NVS	-.075	-.037	-.082	-.019	-.082	1				
7. DM-REALM	.088	.127*	.014	.013	.054	.047	1			
8. Diabetes Knowledge	.086	.100	.011	-.014	.107*	.388**	.083	1		
9. Health Info Seeking	.256**	.159**	.051	.199**	.162**	.106*	.123*	105*	1	
10. Diabetes Self-efficacy	.484**	.366**	.374**	.213**	.251**	-.034	.081	.074	.098	1

SCA=Self-care activities; NVS=Newest Vital Sign; DM-REALM=DM-Rapid Estimate of Adult Literacy in Medicine
* $p < .05$, ** $p < .01$

Research Question 3

Are there differences among diabetes knowledge, health information-seeking behaviors, diabetes self-efficacy or diabetes SCA between those with limited health literacy and those with adequate health literacy?

To assess for statistically significant differences among diabetes knowledge, health information-seeking behaviors, diabetes self-efficacy, and diabetes SCA by health literacy level, independent samples *t*-tests were used. The results of these analyses are presented in Table 15.

Functional health literacy. There was a significant difference in diabetes knowledge, $t(377) = 8.338$, $p < .001$ and health information-seeking behaviors, $t(379) = 3.203$, $p < .01$ between limited and adequate functional health literacy groups. However, no significant differences were found by functional health literacy level in diabetes self-efficacy $t(380) = -.125$, $p > .05$ or diabetes SCA, $t(362) = -1.187$, $p > .05$.

Oral health literacy. There was a significant difference in diabetes knowledge between limited and adequate oral health literacy groups, $t(377) = -2.126$, $p < .05$. No significant differences were identified by oral health literacy level among health information-seeking behaviors, $t(379) = -.993$, $p > .05$, diabetes self-efficacy, $t(380) = -.910$, $p > .05$, or diabetes self-care activities, $t(362) = -1.562$, $p > .05$.

Table 15. *Diabetes knowledge, HISB, diabetes self-efficacy & diabetes SCA by level of health literacy*

	Functional Health Literacy (NVS) (Mean ± *SD*)		*t (df)*	Oral Health Literacy (DM-REALM) (Mean ± *SD*)		*t (df)*
	Limited (score = 0 – 3) *n* = 317	Adequate (score = 4 – 6) *n* = 71		Limited (score = 0 – 75) *n* = 348	Adequate (score = 76 – 82) *n* = 40	
Diabetes Knowledge (0 – 14)	5.1 ± 2.22	7.66 ± 2.00	8.338 (377)***	5.56 ± 2.345	6.40 ± 2.426	-2.126 (377)*
Health Information Seeking (5 – 25)	19.93 ± 2.828	21.13 ± 2.843	3.203 (379)**	20.10 ± 2.841	20.58 ± 3.062	-.993 (379)
Diabetes Self-Efficacy (8 – 80)	55.37 ± 16.189	55.10 ± 15.688	-.125 (380)	55.06 ± 15.715	57.54 ± 19.073	-.910 (380)
Diabetes Self Care Activities (0 – 70)	41.84 ± 13.772	39.59 ± 13.636	-1.187 (362)	41.06 ± 13.752	44.74 ± 13.520	-1.562 (362)

Research Question 4

What are the significant predictors of the level of health literacy among underserved patients with T2DM?

Multiple linear regressions were calculated to predict the level of both functional health literacy (NVS) and oral health literacy (DM-REALM) based on personal characteristics. First, multiple linear regression was used to predict functional health literacy based on the personal characteristics of participants. A significant regression equation was found, $F(11, 154) = 4.611$, $p < .001$, $R^2 = .248$. The significant predictors were gender, $\beta = -.271$, $p < .001$, educational attainment, $\beta = .201$, $p = .007$, and insurance type, $\beta = .253$, $p = .004$.

Table 16. *Multiple regression to predict Functional HL - NVS (n = 166)*

Predictor	B	β	*p*
Age	-0.002	-0.071	.385
Gender (1=female, 2=male)	-0.153	-0.271	<.001
Language (1=English, 2=Spanish)	0.072	0.121	.315
Acculturation	0.008	0.205	.088
Income	0.022	0.090	.265
Employment status	0.008	0.040	.614
Housing type	-0.001	-0.004	.953
*Educational attainment	0.034	0.201	.007
Marital status (1=living with others, 2=living alone)	-0.002	-0.003	.973
Years with T2DM	-0.003	-0.086	.264
Insurance type	0.052	0.253	.004
Model Summary	$R^2 = .248$; F = 4.611; $p < .001$		

*Note. * Missing data excluded (n=166).*

A second multiple linear regression was then calculated to predict the level of oral health literacy (DM-REALM) based on demographic characteristics. A significant regression equation was found, $F(11, 154) = 4.367$, $p < .001$, $R^2 = .238$. The significant predictors were gender, $\beta = -.235$, $p = .004$, employment status, $\beta = -.176$, $p = .043$, and years with T2DM, $\beta = .182$, $p = .028$.

Table 17. *Multiple regression to predict Oral Health Literacy – DM-REALM (n = 166)*

Predictor	B	β	*p*
Age	0.090	0.036	0.681
Gender (1=female, 2=male)	-12.402	-0.235	0.004
Language (1=English, 2=Spanish)	-1.463	-0.026	0.838
Acculturation	0.256	0.068	0.594
Income	1.494	0.065	0.449
Employment status	-5.737	-0.176	0.043
Housing type	-.0834	-0.037	0.652
*Educational attainment	0.231	0.015	0.855
Marital status (1=living with others, 2=living alone)	-1.543	-0.030	0.733
Years with T2DM	0.544	0.182	0.028
Insurance type	2.767	0.144	0.124
Model Summary	$R^2 = .238$; F = 4.367; $p < .001$		

*Note. * Missing data excluded (n=166).*

Research Question 5

What are the significant predictors of diabetes SCA among underserved patients with T2DM?

Two regression analyses were used for this analysis – the first incorporated functional health literacy as a potential predictor variable and the second incorporated oral health literacy as a potential predictor variable. For both regression analyses, 356 cases were included. Table 18 presents the results of the hierarchical regression for prediction of diabetes SCA among underserved patients with T2DM, using the NVS as the health literacy measure. In Model 1, functional health literacy, DM knowledge, and health information-seeking behaviors accounted for 9.0% of the variance in diabetes SCA of underserved patients with T2DM. Model 1 explained a significant amount of the variability, $F(3, 352) = 11.726$, $p < .001$, $R^2 = .09$. The significant predictors were functional health literacy, $\beta = -.16$, $t = -2.88$, $p < .01$, diabetes knowledge, $\beta = .14$, $t = 2.41$, $p < .05$, and health information seeking behaviors, $\beta = 0.25$, $t = 4.95$, $p < .001$.

In Model 2, adding diabetes self-efficacy accounted for 29.0% of the variance in diabetes SCA among underserved patients with T2DM. In Model 2 with the variable of diabetes self-efficacy, the R^2 change was significant, $\Delta F(4, 351) = 23.71$, $p < .001$, $\Delta R^2 = .20$. The final significant predictors were functional health literacy, $\beta = -1.00$, $t = -2.56$, $p < .011$, health information-seeking behaviors, $\beta = .21$, $t = 4.59$, $p < .001$, and diabetes self-efficacy, $\beta = .45$, $t = 9.84$, $p < .001$.

Table 18. *Hierarchical Regression to predict diabetes self-care activities using NVS (n = 356)*

	Model 1				Model 2			
	B	β	*t*	*p*	B	β	*t*	*p*
Functional HL (NVS)	-1.27	-0.16	-2.88	.004	-1.00	-0.13	-2.56	.011
Diabetes knowledge	0.78	0.14	2.41	.016	0.53	0.09	1.86	.064
Health information-seeking	1.25	0.25	4.95	<.001	1.03	0.21	4.59	<.001
	$R^2 = .09$; $R^2_{adj} = .08$; $F = 11.726$; $p < .001$							
Diabetes self-efficacy					0.38	0.45	9.84	<.001
					$R^2 = .29$; $R^2_{adj} = .28$; $F = 35.439$; $p < .001$ R^2 change = .20; F change = 23.713; $p < .001$			

Table 19 presents the results of the second hierarchical regression for prediction of diabetes SCA among underserved patients with T2DM using the DM-REALM as the health literacy measure. In Model 1, oral health literacy, diabetes knowledge, and health information-seeking behaviors accounted for 7.0% of the variance in diabetes SCA of underserved patients with T2DM. Model 1 explained a significant amount of the variability $F(3, 352) = 9.269$, $p < .001$, $R^2 = .09$. Only one significant predictor was identified - health information seeking behaviors, $\beta = 0.24$, $t = 4.68$, $p < .001$.

In Model 2, adding diabetes self-efficacy accounted for 28.0% of the variance in diabetes SCA among underserved patients with T2DM. In Model 2, with the variable of diabetes self-efficacy, the R^2 change was significant, $\Delta F(4, 351) = 98.62$, $p < .001$, $\Delta R^2 = .20$. The final significant predictors were health information seeking behaviors, $\beta = .20$, $t = 4.30$, $p < .001$, and diabetes self-efficacy, $\beta = .46$, $t = 9.93$, $p < .001$.

Table 19. *Hierarchical Regression to predict diabetes self-care activities using DM-REALM (n = 356)*

	Model 1				Model 2			
	B	B	*t*	*p*	B	β	*t*	*p*
Oral HL (DM-REALM)	0.03	0.05	0.99	.321	0.02	0.04	0.77	.443
Diabetes knowledge	0.38	0.07	1.27	.207	0.22	0.04	0.83	.406
Health information-seeking	1.20	0.24	4.68	<.001	0.98	0.20	4.30	<.001
	R^2 = .07; R^2_{adj} = .06; F = 9.269; p < .001							
Diabetes self-efficacy					0.39	0.46	9.93	<.001
					R^2 = .28; R^2_{adj} = .27; F =33.393; p < .001 R^2 change = .20; F change = 98.620; p < .001			

Research Question 6

Do health information-seeking behaviors and diabetes self-efficacy mediate the effects of health literacy on diabetes SCA among underserved patients with T2DM?

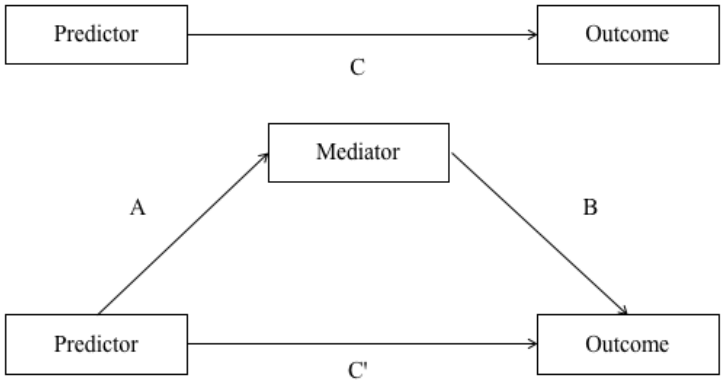
Two measures of health literacy were used in this dissertation study. Therefore, both required inclusion in the mediation analysis, but in separate analyses. For clarity, functional health literacy was used in the first mediation analysis and oral health literacy was used in the second mediation analysis. This research question was analyzed using two separate inquiries:

a) *Do health information-seeking behaviors and diabetes self-efficacy mediate the effects of functional health literacy on diabetes SCA among underserved patients with T2DM?*
b) *Do health information-seeking behaviors and diabetes self-efficacy mediate the effects of oral health literacy on diabetes SCA among underserved patients with T2DM?*

The procedure outlined by Baron & Kenny (1986) was followed to perform each mediation analysis. The mediation analysis method is illustrated in Figure 4 below. Baron & Kenny (1986) outline four steps using three regression analyses to establish the mediation effect of a variable between an independent and dependent variable. Path C represents a significant relationship between the independent (predictor) and dependent (outcome) variables and this is the first step in the mediation process. The second step (Path A) is to show that the predictor variable is correlated with the mediator variable

(treating the mediator variable as an outcome variable). The third step is to establish that there is a correlation between the mediator variable and the outcome variable (Path B). The fourth step is to assess whether the strength of the relationship between the predictor and outcome variables is significantly reduced when the mediator is added to the model. Complete mediation is evident when the effect of the predictor variable on the outcome variable equals zero when controlling for the mediator (Path C'). In the figures of each mediation analysis presented in this section, dashed lines are used for non-significant pathways and solid lines represent significant pathways.

Figure 4. *Mediation analysis as proposed by Baron & Kenny (1986)*

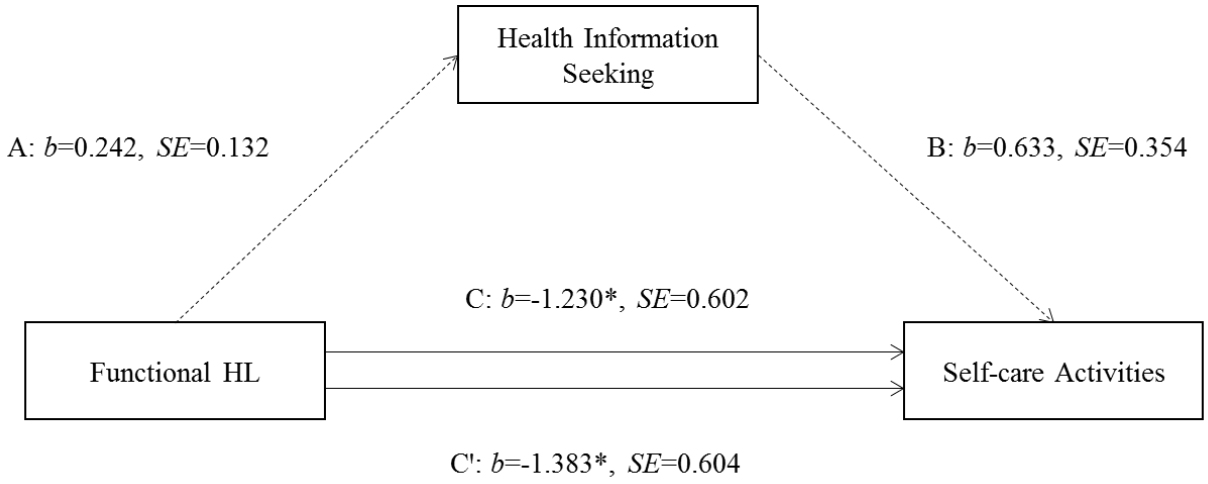


a) Do health information-seeking behaviors and diabetes self-efficacy mediate the effects of functional health literacy on diabetes SCA among underserved patients with T2DM?

To address this research question, two separate mediation analyses were performed. First, health information-seeking behaviors were included as a mediator. Those results are presented first. Then, diabetes self-efficacy was included as a mediator. Those results are presented second.

Health information-seeking behaviors. The first step of mediation analysis is to determine that there is a relationship between the dependent and independent variable that may be mediated. There was no significant relationship between functional health literacy and health information-seeking behaviors (Path A), therefore no mediation analysis could be conducted on the variable health information-seeking behaviors with functional health literacy in this study (Figure 5).

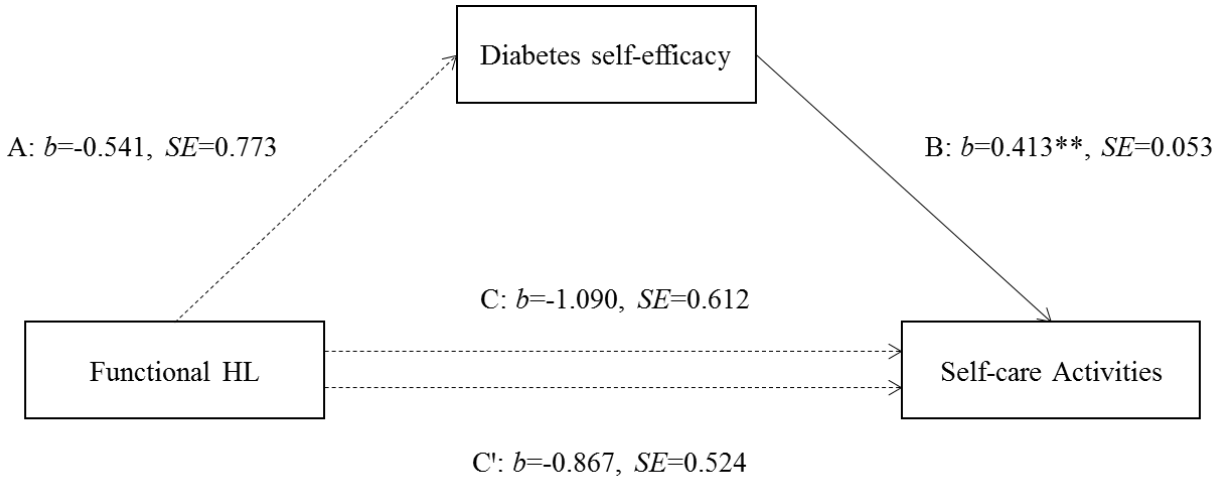
Figure 5. *Relationship between Functional HL and SCA by health information-seeking behaviors*



* $p < .05$, ** $p < .01$

Diabetes self-efficacy. Similar to the outcome of the first attempt at identifying mediation, the first step of the mediation analysis revealed that there was no significant relationship between functional health literacy and diabetes self-efficacy (Path A), therefore no mediation analysis could be conducted on the variable diabetes self-efficacy with functional health literacy in this study (Figure 6).

Figure 6. *Relationship between Functional HL and SCA by diabetes self-efficacy*



* $p < .05$, ** $p < .01$

b) Do health information-seeking behaviors and diabetes self-efficacy mediate the effects of oral health literacy on diabetes SCA among underserved patients with T2DM?

To address this research question, two separate mediation analyses were performed. First, health information-seeking behaviors were included as a mediator. Those results are presented first. Then, diabetes self-efficacy was included as a mediator. Those results are presented second.

Health information-seeking behaviors. To examine whether *health information-seeking behaviors* mediated the relationship between oral health literacy and diabetes SCA, regression-based mediation analyses estimating all paths were performed using

Hayes' PROCESS macro in SPSS (2013). To estimate the effect size of the indirect effects of the independent variable (oral health literacy) on the dependent variable (SCA), this method uses bootstrapping procedures. A mediation model was used, with health information-seeking behaviors as a mediator.

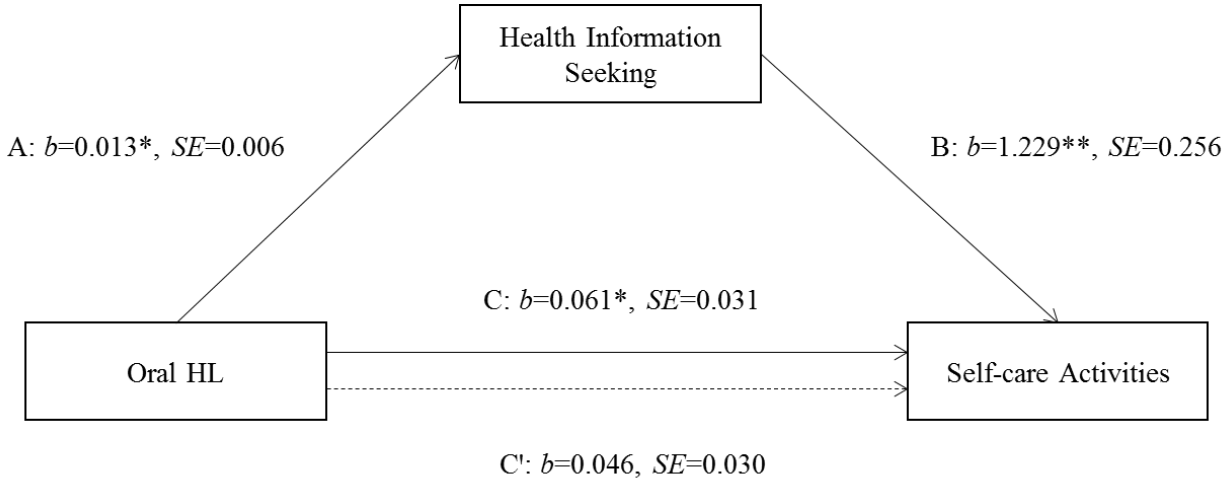
The direct effect of the independent variable on diabetes SCA was determined by the regression coefficient magnitude and significance ($p < .05$), and the indirect effect through health information-seeking was determined by a significant effect size (95% bootstrap CI does not include 0). Since there were significant correlations between demographic variables and oral health literacy, three covariates (gender, employment status, and years with T2DM) were included in the mediator model.

Using the mediation model shown in Figure 7, health information-seeking behaviors mediated the relationship between health literacy and diabetes SCA. The mediation results, including regression coefficients, standard errors and *p*-values are presented in Table 20. Regression analyses confirmed the significant influence of oral health literacy on diabetes SCA (Path C, $b = 0.061$, $SE = 0.031$, $p < .05$), as well as health information-seeking behaviors (Path A, $b = 0.013$, $SE = 0.006$, $p < .05$). Regression analyses also revealed that health information-seeking behaviors were significantly related to diabetes SCA (Path B, $b = 1.229$, $SE = 0.256$, $p < .001$). When health information-seeking behaviors was included as a mediator on diabetes SCA, the effect of oral health literacy was reduced: $b = 0.046$, $SE = 0.030$, $p > .05$ (Path C').

Oral health literacy exhibited an indirect effect on diabetes SCA through health information-seeking behaviors. This indirect effect of oral health literacy on diabetes

SCA was significant as indicated by the 95% CI (0.001, 0.037) using 5,000 bootstrap estimations (Path AB). The overall model was significant with an adjusted R^2 of .085, $p <$ .01.

Figure 7. *Relationship between Oral HL and SCA by health information-seeking behaviors*



* $p < .05$, ** $p < .01$

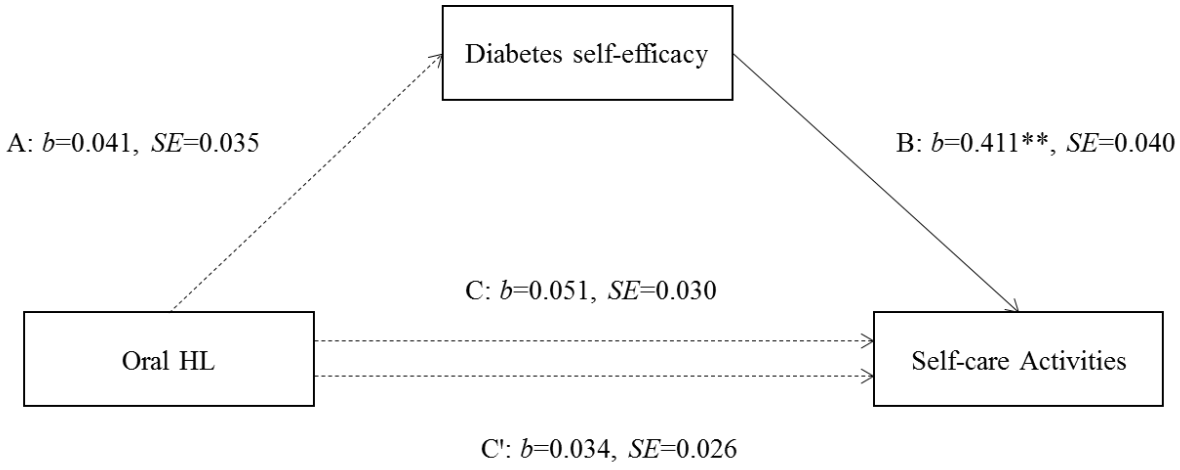
Although oral health literacy did not have a significant direct effect on diabetes SCA ($b = 0.046$, $p < .132$), health information-seeking behaviors was identified as a mediator in the relationship between oral health literacy and diabetes SCA, $b = 0.015$, 95% CI = 0.001, 0.037.

Table 20. *Mediation Results of Oral HL on SCA through health information-seeking behaviors*

	Path	*b (SE)*
Variance explained 8.5%		
Total effect	C = AB + C’	0.061 (0.031)
Oral health literacy → Health information-seeking	A	0.013 (0.006)
Health information seeking → Self-care activities	B	1.229 (0.256)
Direct effect	C’	0.046 (0.030)
Indirect effect (Health information-seeking)	C – C’	0.015 (0.009)

Diabetes self-efficacy. Once again, the first step of the mediation analysis revealed that there was no significant relationship between oral health literacy and diabetes self-efficacy (Path A), therefore no mediation analysis could be conducted on the variable diabetes self-efficacy with oral health literacy in this study (Figure 8).

Figure 8. *Relationship between Oral HL and SCA by diabetes self-efficacy*



* $p < .05$, ** $p < .01$

SUMMARY

Among the 388 participants with T2DM in this study, the majority lived at or near the poverty level, in non-permanent housing, were under-educated and publicly insured. Approximately 32% of participants were Spanish-speaking. Health literacy scores among participants were very low. Personal characteristics that correlated with health literacy level included age, gender, language, acculturation, income, employment status, insurance, education, and marital status. Significant differences emerged among personal characteristics including language, income, education, marital status, employment status and insurance by level of health literacy. Significant predictors of functional health literacy included gender, education, and insurance type. Significant predictors of oral health literacy included gender, employment status, and years with T2DM.

Bivariate correlations among major variables revealed several statistically significant relationships. Diabetes SCA were correlated to diabetes self-efficacy and health information-seeking behaviors. Functional health literacy was correlated to diabetes knowledge, as well as health information-seeking behaviors. Oral health literacy was significantly correlated with health information-seeking behaviors. Using hierarchical multiple regression for prediction of diabetes SCA, functional health literacy, health information-seeking behaviors and diabetes self-efficacy accounted for 29% of the variance in diabetes self-care activities. Finally, in mediation analyses, health information-seeking behaviors was identified as a mediator in the relationship between oral health literacy and diabetes SCA.

Chapter Five: Discussion, Implications and Conclusion

SCA are an important part of self-management for people with T2DM, but prior to this study, the empirical relationship between health literacy levels and diabetes SCA has remained unclear. Previous studies have failed to address this relationship in the following ways: (1) varying operationalization of both health literacy and diabetes SCA; (2) inconsistent use of theoretical frameworks; (3) erratic inclusion of people from underserved communities – notably non-English speakers from Mexico-bordering states; and (4) inability to identify direct or indirect pathways of the effects of health literacy on diabetes SCA. The research for this dissertation was therefore undertaken to describe health literacy levels and SCA in a sample of underserved people with T2DM, and, using a highly generalizable, parsimonious theoretical model of health behavior, to specify pathways of the influence of health literacy on SCA.

The data for this study were collected from participants in a multi-site, cross-sectional study of meaningful relationships between health literacy and diabetes SCA in underserved patients. A total of 388 participants were recruited from six clinics within the largest federally qualified health center in central Texas. The surveys were administered in person by a Spanish or English-speaking RA. If a participant expressed or exhibited any difficulty reading the survey, the survey was administered by interview. Otherwise, participants independently completed the survey with an RA sitting beside them – available for assistance or questions. The surveys included demographic questions and tools to measure functional health literacy, oral health literacy, diabetes knowledge,

health information-seeking behaviors, diabetes self-efficacy, and diabetes SCA. The survey took approximately 30 minutes to complete.

Sequential data analysis was conducted with descriptive statistics that included the psychometric properties of each scale, *t*-tests, chi-square, and inferential statistics such as bivariate and multivariate analysis, using SPSS 25.0. In addition, an SPSS macro from Hayes (2013) was utilized for the mediation analysis.

DISCUSSION

Sample Characteristics

Among the 388 participants who participated in this multi-site study, the median age was 53.07 years (*SD* = 10.33); approximately two thirds were female. According to a 2017 report from the Centers for Disease Control and Prevention (CDC, 2017), more than half of all new cases of diabetes occur among people from 45 to 64 years of age, with equal prevalence for both men and women. The majority of participants chose to complete the questionnaire in English, but 32.7% did so in Spanish. This is considerably higher than the state and county level prevalence of Spanish speakers. According to census data (U.S. Census Bureau, 2018), approximately 29% of Texans speak Spanish at home, but Spanish speaking is less prevalent in Travis County (22%). Although very few studies addressing health literacy and health outcomes among people with diabetes have included Spanish speakers as participants, those that have done so report a similar proportion (one third) of Spanish speakers (Sarkar et al., 2006; Schillinger et al., 2002; Seligman et al., 2005). Alternatively, some researchers have chosen to include only Spanish speakers in their samples (Kenya et al., 2015; Smith-Miller et al., 2016; White et

al., 2011). It is important to note that among the 25 studies reviewed for this one, 19 excluded Spanish speakers altogether in their sample. The findings from this dissertation study therefore add to the growing body of literature about how Spanish-speaking patients interact with the American healthcare system. Although speaking Spanish is not wholly indicative of Hispanic ethnicity, it can provide important information about study participants. According to the CDC, people of Hispanic origin have a much higher age-adjusted incidence of diabetes than do non-Hispanic whites (8.4 vs. 5.7 per 1,000 persons).

The income level of participants in this study was very low – most reported an annual income of less than $10,000. Oversampling participants that are resource poor is common in such research (Al Sayah et al., 2015; Kim et al., 2004; Mbaezue et al., 2010; Morris et al., 2006; Rothman et al., 2004; Rothman et al., 2005; Sarkar et al., 2006; Schillinger et al., 2002; White et al., 2011), and given the negative impact of socioeconomic status on diabetes outcomes, a high rate of low-income participants is not surprising.

Approximately 58% of participants in this study had completed high school or a higher level of advanced education. Compared with county and state level education attainment data, this percentage is considerably lower, with Travis County at 88.8% and Texas at 82.9% (Table 21). However, this low education attainment (around 40% with no higher than a high school degree) aligns with other studies (Al Sayah et al., 2015; Bowen et al., 2013; Brega et al., 2012; Cavanaugh et al., 2008; Cavanaugh et al., 2009; Graumlich et al., 2016; Heinrich, 2012; McCleary-Jones, 2011; Osborn et al., 2009), and

some studies have reported even higher proportions of less educated participants (Mancuso, 2010; Mbaezue et al., 2010; Morris et al., 2006; Rothman et al., 2004; Rothman et al., 2005; Schillinger et al., 2002), with one as high as 90% (White et al., 2011).

Table 21. *Comparison of sample participant demographic data with Travis County & Texas*

	Texas	Travis County	This Sample
Age (Median)	34.5	33.7	53.07
Spanish-speakers (%)	29	22	32.7
Annual Income (Median)	$56,565	$70,158	$\leq$ $10,000
Education Attainment (% HS or higher)	82.9	88.8	58.2
Marital Status (% married)	51	45	34.9

In summary, people with limited economic resources are at risk for underutilized health care services due to multiple factors including location (rural vs. urban), inability to communicate effectively (English-speaking vs. other languages), lack of financial resources, limited educational attainment, advanced age and state of health (U.S. Department of Health & Human Services, 2018). The participants in this study were older (when compared with local census data), but comparable in age to patients included in similar studies. They spoke Spanish at a higher rate, earned considerably less and reported fewer years of education than did their local (Travis County) and statewide (Texas) peers (Table 21). Therefore, this sample was adequately representative of populations with T2DM who suffer from limited economic resources.

Health Literacy

Overall, health literacy among study participants was exceptionally low. Only 18.3% of participants exhibited adequate functional health literacy on the NVS. Even fewer participants (10.3%) exhibited adequate oral health literacy on the DM-REALM. The DM-REALM scores were lower than in previous studies with similar aims (using the REALM to measure oral health literacy). Graumlich et al. (2016) reported that 22% of a sample of 674 patients with T2DM exhibited limited oral health literacy, but participants in their sample were mostly white high school graduates with annual incomes greater than $20,000. Similarly, Bowen et al. (2013) found that 11% of 144 patients with T2DM exhibited limited oral health literacy, but again, participants were mostly white, high school educated with incomes greater than $20,000. Cavanaugh et al. (2008) reported that 69% of 398 patients with T2DM scored adequately on the REALM, but echoing the other studies, most of the participants were white, high school educated with incomes greater than $20,000. It is worth noting, as well, that none of these studies included Spanish-speaking participants.

The results on the NVS from participants in this study, however, were more closely aligned with those of previous studies – although still lower. Heinrich (2012) reported that 65% of a small, racially diverse sample of 52 patients with T2DM exhibited limited functional health literacy and Piatt et al. (2014) reported that 52% of a sample of 70 African-Americans with T2DM scored adequately on the NVS. Both studies, though, had small sample sizes, which may have contributed to this discrepancy.

Among studies with similar aims, but using instruments other than the REALM and the NVS, the S-TOFHLA or TOFHLA were the most common measures of health literacy and participant's performance varied. Some studies reported that the majority of participants (over 50%) exhibited limited health literacy as measured by the S-TOFHLA (Sarkar et al., 2006: Schillinger et al., 2002; Seligman et al., 2005), whereas others found that the opposite (Kim et al., 2004; Mancuso et al., 2010; Mbaezu et al., 2010; Morris et al., 2006; White et al., 2011). Although the S-TOFHLA was the health literacy instrument most commonly used, its popularity seems to have waned over the last 5 years. The last published study of health literacy among people with T2DM that used the S-TOFHLA is from 2011. In the last 5 years, the NVS, REALM, SAHL and 3-item HL scale have been more dominant.

The skewed distribution of scores from this sample on the NVS and the DM-REALM led to less variance and may have decreased the ability to find statistically significant relationships among the variables. Participant's scores on the NVS were markedly positively skewed, which may indicate that the NVS is not an ideal instrument for research for this population. Future researchers should carefully consider their choice of health literacy instrument based on the population they are working with. Additionally, with little agreement among researchers about what health literacy instrument to use, development of a new, more holistic instrument may be needed.

Relationships among Study Variables

Personal characteristic data were partitioned into three different categories: (1) intrinsic personal characteristics, (2) indicators of financial status, and (3) indicators

relating to health. The following section describes the results of analyses related to personal characteristics and health literacy, as well as comparisons or contrasts with the literature.

Health Literacy & Intrinsic Personal Characteristics

Intrinsic personal characteristics were age, gender, language, acculturation, education attainment and marital status. The relationships between intrinsic personal characteristics and health literacy are described below.

Age. Age was significantly and negatively related to functional health literacy, r = -.173, $p < .05$, but not to oral health literacy. Chi-square tests revealed that there were no statistically significant differences in age based on either functional or oral health literacy level. In multiple linear regression analysis, age was not identified as a significant predictor for either functional or oral health literacy.

This inverse relationship between age and health literacy echoes the findings of previous studies (Bowen et al., 2013; Cavanaugh et al., 2008; Kim et al., 2004; Mancuso, 2010; Mbaezue et al., 2010; Morris et al., 2006; Piatt et al., 2014; Rothman et al., 2004; Schillinger et al., 2002). However, a scan of the literature did reveal one study of African American people with diabetes (McCleary-Jones, 2011) that failed to identify a relationship with age. The small homogenous sample in that study may have contributed to the inability to identify a meaningful relationship between age and health literacy.

The findings of the present study are consistent with the findings of previous studies: as age increases, health literacy decreases.

Gender. In bivariate correlations, gender was significantly correlated with functional health literacy, $r = -.170$, $p < .01$ and oral health literacy, $r = -.101$, $p < .05$. Women were more likely to have higher health literacy on both instruments. Chi-square tests revealed that there were no statistically significant differences in gender based on functional or oral health literacy. However, gender was a significant predictor of both functional and oral health literacy using multiple linear regression analysis.

Research Question 4 appraised the predictive relationship between variables from the correlation results, personal characteristics (age, gender, language, acculturation, education attainment, marital status), financial indicators (income, employment, housing type), and health indicators (health insurance type, years with T2DM) that were projected to contribute significantly to functional health literacy using linear regression. A significant regression equation was found, $F(11, 154) = 4.611$, $p < .001$, $R^2 = .248$. The significant predictors of functional health literacy included gender, $\beta = -.271$, $p < .001$, educational attainment, $\beta = .201$, $p = .007$, and insurance type, $\beta = .253$, $p = .004$. The same process was repeated for variables expected to contribute significantly to oral health literacy using linear regression. A second significant regression equation was found, $F(11, 154) = 4.367$, $p < .001$, $R^2 = .238$. The significant predictors of oral health literacy included gender, $\beta = -.235$, $p = .004$, employment status, $\beta = -.176$, $p = .043$, and years with T2DM, $\beta = .182$, $p = .028$.

The literature shows some conflicting results for the association between gender and health literacy. Two studies have reported a positive association between female gender and health literacy scores among patients with diabetes. Piatt et al. (2014) used the

NVS and Al Sayah et al. (2015) used the Chew 3-question HL screener and found that female gender was associated with higher HL scores. However, Bowen et al. (2013) found that lower numeracy scores (as measured by the DNT) were associated with female gender. Although the correlations between gender and both oral and functional health literacy identified in this study were small, the predictive nature of gender in this population warrants further investigation.

Language. Of the 388 study participants, 127 (32.7%) completed the survey in Spanish. Overall, only 4% of Spanish speakers exhibited adequate functional health literacy on the NVS. The NVS uses the nutritional information label from a container of ice cream, and for this study, the label was translated into Spanish. However, it is worth noting that most nutrition labels on foods in the U.S. are not translated into Spanish. This study did not address how often participants used nutritional food labels to make diet choices, but the scores on the NVS could provide information about how comfortable people are with using food labels. Without translation into Spanish, it is questionable to what degree Spanish speakers use food labels to make important diet decisions. Similarly, only 11% of Spanish-speaking participants scored adequately on the DM-REALM. This tool is based on one's ability to enunciate words properly, and for this study, the tool was provided in Spanish. Bilingual RAs carefully assessed the pronunciation of each word and marked words as correct or incorrect. The words proved difficult for many, which may indicate a lack of familiarity with diabetes management.

English speaking/reading ability was positively and significantly correlated with functional health literacy, $r = .222$, $p < .05$ and there was a significant difference between

those with limited and those with functional health literacy based on language, $\chi^2 = 23.270$, $p < .001$. No significant correlations or differences in health literacy were found by oral health literacy. Additionally, language was not identified as a significant predictor for either functional or oral health literacy using multiple linear regression analysis.

Only one previous study (Schillinger et al., 2002) has reported a significant relationship between health literacy scores and language among patients with diabetes – Spanish speakers scored significantly lower scores on the S-TOFHLA when compared with English-speaking participants. Five studies with similar aims included Spanish speakers in their sample, but they either did not report findings related to differences in HL based on language ability (Sarkar et al., 2006; Seligman et al., 2005) or included only Spanish speakers in the sample and therefore could not report differences between language groups (Kenya et al., 2015; Smith-Miller et al., 2016; White et al., 2011).

Limited health literacy has been correlated with Spanish speaking in a number of studies outside of the diabetes literature, and the findings of this study support the need for more inquiry regarding this relationship in this sensitive population. As the population of Spanish speakers continues to grow in this country, so too should the efforts to include them in healthcare research. It is vitally important for researchers to better understand how this population navigates the complex U.S. healthcare system.

Acculturation. Bivariate correlations revealed a statistically significant positive relationship between level of acculturation and functional health literacy, $r = .287$, $p < .05$, but not oral health literacy. Chi-square tests revealed no statistically significant differences in acculturation based on health literacy level. Finally, acculturation was not

found to be a significant predictor of either functional or oral health literacy. In bivariate correlations, however, acculturation level and language were strongly and significantly correlated, $r = .729$, $p < .05$. Acculturation and English-speaking proficiency go hand-in-hand, and the similarities in between the correlations between the two and health literacy are logical.

The relationship between health literacy and acculturation is highly understudied among underserved patients with diabetes. Acculturation level exhibited a statistically significant correlation with HL level in only one previous study with a similar population of patients (White et al., 2011). Echoing the previous argument regarding the need to include more Spanish speakers in studies, it would be equally important to understand the extent to which these non-English speakers are acculturated to the American culture.

Education attainment. Education attainment was significantly positively correlated with functional health literacy, $r = .313$, $p < .05$, but not oral health literacy. There was a significant difference in education attainment based on functional health literacy level, $\chi^2 = 18.570$, $p < .001$. Education was also a significant predictor of functional health literacy using multiple linear regression analysis.

Research Question 4 appraised the predictive relationship between variables from the correlation results, personal characteristics (age, gender, language, acculturation, education attainment, marital status), financial indicators (income, employment, housing type), and health indicators (health insurance type, years with T2DM) that were projected to contribute significantly to functional health literacy using linear regression. A significant regression equation was found, $F(11, 154) = 4.611$, $p < .001$, $R^2 = .248$. The

significant predictors included gender, $\beta = -.271$, $p < .001$, educational attainment, $\beta = .201$, $p = .007$, and insurance type, $\beta = .253$, $p = .004$.

Education attainment has exhibited a statistically significant correlation with level of HL in previous studies of similar patient populations (Al Sayah et al., 2015; Bowen et al., 2013; Heinrich, 2012; Kim et al., 2004; Mbaezue et al., 2010; Miser et al., 2013; Morris et al., 2006; Schillinger et al., 2002; White et al., 2011). Although education level is an important correlate of health literacy, it does not fully explain the variance among participants in this study. Additionally, education level can be difficult to ascertain among immigrants to the U.S., and education equivalencies aren't always clear.

Marital status. Marital status was significantly correlated with functional health literacy, $r = .126$, $p < .05$, but not with oral health literacy. Being unmarried (single, divorced, or widowed) was associated with a higher level of functional health literacy. There were significant differences in marital status (partnered vs. un-partnered) by functional health literacy level, $\chi^2 = 4.710$, $p < .05$. Marital status was not identified as a significant predictor of either functional or oral health literacy.

The relationship between marital status and HL among people with diabetes has not been extensively explored in the literature, but Morris et al. (2006) found that a higher level of HL was associated with being married. In the present study, however, participants who were unmarried (single, divorced or widowed) were more likely to have higher HL. Age was significantly correlated with marital status in this study's participants. Additionally, the older the participants, the more likely they were married. Considering the inverse relationship between age and health literacy, age may have been

a contributing factor to the findings of the relationship between marital status and health literacy in this study.

Summary. Each of the intrinsic personal characteristics exhibited a statistically significant correlation with functional health literacy, including age, gender, language, acculturation, education attainment, and marital status. Participants who were younger, female, unmarried, those who chose to take the survey in English, those with a higher level of acculturation, and those with more years of education were more likely to have a higher level of functional health literacy. Only gender exhibited a statistically significant correlation with oral health literacy level. Echoing the results of the NVS, female participants were more likely to have a higher level of oral health literacy. These relationships are consistent with findings from other studies in similar populations of patients with diabetes, but do also reveal some contrasts. These personal characteristics are all important social determinants of health and their relationship with health literacy is an important takeaway from this study.

Health Literacy and Indicators of Financial Status

Indicators of financial status were divided into three different categories: (1) income; (2) employment; and (3) housing type. The results of analyses related to financial status indicators and health literacy, as well as comparisons or contrasts with existing literature, are presented below.

Income. Overall, there was limited variability in income among participants due to the fact that the sample was recruited from clinics within a federally qualified health

center. As noted previously, FQHCs are intended as safety net healthcare facilities and serve primarily underserved patients. Bivariate correlations revealed a statistically significant positive correlation between annual income and functional health literacy, $r = .116$, $p < .05$, but not between annual income and oral health literacy. There were statistically significant differences in income based on functional health literacy level, $\chi^2 = 23.203$, $p < .001$. However, income was not identified as a significant predictor of either functional or oral health literacy.

Higher income was correlated with a higher level of functional health literacy. In studies with similar aims and sample participants, income has exhibited the same positive effect on HL (Bowen et al., 2013; Cavanaugh et al., 2008; Kim et al., 2004; Morris et al., 2006; Rothman et al., 2004; White et al., 2011). Income was significantly correlated with education attainment in this sample of participants, echoing a widely accepted relationship between the two.

Employment. Employment status (employed vs. unemployed) was not significantly related to functional health literacy, but it was significantly related to oral health literacy, $r = -.160$, $p < .05$. Employment status differed significantly by oral health literacy status, $\chi^2 = 3.862$, $p < .05$. In a multiple linear regression model, employment was identified as a predictor that explained a significant amount of the variance in oral health literacy.

Research Question 4 appraised the predictive relationship between variables from the correlation results, personal characteristics (age, gender, language, acculturation, education attainment, marital status), financial indicators (income, employment, housing

type), and health indicators (health insurance type, years with T2DM) that were projected to contribute significantly to oral health literacy using linear regression. A significant regression equation was found, $F(11, 154) = 4.367$, $p < .001$, $R^2 = .238$. The significant predictors of oral health literacy included gender, $\beta = -.235$, $p = .004$, employment status, $\beta = -.176$, $p = .043$, and years with T2DM, $\beta = .182$, $p = .028$.

In contrast to the non-significant findings related to employment status and level of functional HL in this study, but in agreement with the findings related to oral health literacy, Al Sayah et al. (2015) reported a statistically significant relationship between the two, in that those who were employed were more likely to have a higher level of HL (as determined by the Chew 3-item HL screener).

Housing type. No significant correlation was found between housing type and functional or oral health literacy. Additionally, no significant differences were found regarding type of housing based on health literacy level. Overall, there was very little variability in housing among study participants. Only 18.9% of participants reported that they owned their home. The remainder of the sample was renting a home (40.7%), living in public housing (7.9%), living with relatives or friends (24.4%), or in another living arrangement (8.1%). This lack of variability in type of housing among participants may have influenced the result of the correlation analysis.

Summary. Two financial indicators exhibited a statistically significant correlation with health literacy – income with functional health literacy and employment status with oral health literacy. Housing type was not correlated with either functional or

oral health literacy. Participants who earned more and were employed were more likely to have a higher level of health literacy.

Health Literacy and Health Indicators

Two indicators of health were included in this study: insurance status and number of years living with T2DM. The following section presents the results of analyses related to health indicators and health literacy, as well as comparisons or contrasts with existing literature.

Health insurance status. Health insurance status was significantly related to oral health literacy, $r = .138$, $p < .05$, but not to functional health literacy. However, there were significant differences in health insurance status by functional health literacy level, $\chi^2 = 6.930$, $p < .01$, although the same difference did not prevail by oral health literacy level. Insurance type was identified as a significant predictor of functional health literacy.

Research Question 4 appraised the predictive relationship between variables from the correlation results, personal characteristics (age, gender, language, acculturation, education attainment, marital status), financial indicators (income, employment, housing type), and health indicators (health insurance type, years with T2DM) that were projected to contribute significantly to functional health literacy using linear regression. A significant regression equation was found, $F(11, 154) = 4.611$, $p < .001$, $R^2 = .248$. The significant predictors included gender, $\beta = -.271$, $p < .001$, educational attainment, $\beta = .201$, $p = .007$, and insurance type, $\beta = .253$, $p = .004$.

Previous studies have also sought to determine the relationship between insurance status and health literacy, although results are conflicting. Some studies have identified a negative relationship between health literacy among patients with T2DM and being either uninsured or publicly insured (Mbaezue et al., 2010; Morris et al., 2006; Schillinger et al., 2002), but one has reported the absence of a relationship between the two (Al Sayah et al., 2015). Outside of the diabetes literature, in a recently published study regarding health literacy and insurance status among Californians, limited health literacy was a significant predictor of being uninsured (Sentell, 2012).

Number of years with T2DM. Length of time living with a diabetes diagnosis was not significantly related to either functional or oral health literacy in bivariate analysis. However, in a multiple linear regression model aimed at predicting oral health literacy, number of years with T2DM was identified as a statistically significant predictor.

Research Question 4 appraised the predictive relationship between variables from the correlation results, personal characteristics (age, gender, language, acculturation, education attainment, marital status), financial indicators (income, employment, housing type), and health indicators (health insurance type, years with T2DM) that were projected to contribute significantly to oral health literacy using linear regression. A significant regression equation was found, $F(11, 154) = 4.367$, $p < .001$, $R^2 = .238$. The significant predictors of oral health literacy included gender, $\beta = -.235$, $p = .004$, employment status, $\beta = -.176$, $p = .043$, and years with T2DM, $\beta = .182$, $p = .028$.

Although scarcely reported in the literature, duration of diabetes among study participants has been associated with health literacy in studies with similar aims (Mbaezue et al., 2010; Morris et al., 2006; Schillinger et al., 2002).

Summary. In summary, health indicators were significant contributors to variance in both functional and oral health literacy. Insurance status played an important role in functional health literacy, and length of time living with diabetes contributed to oral health literacy. This section of the results highlights the impact of the social determinants of health on health literacy. Although the homogeneity and non-normal distribution of many of these variables may have decreased the ability to identify all of the meaningful relationships among socioeconomic factors and health literacy, some important relationships have been identified and are important takeaways from this study.

Relationships Among IMB Theoretical Constructs

The following section presents the results of any analyses related to the relationships organized by the information-motivation-behavioral (IMB) skills theoretical framework, as well as any comparisons or contrasts with existing literature.

Health Literacy and IMB Theoretical Constructs

Information *(functional or oral health literacy and diabetes knowledge)*

Functional health literacy and diabetes knowledge. Functional health literacy (as measured by the NVS) exhibited a significant weak correlation with diabetes knowledge, $r = .388$, $p < .01$. Participants with adequate functional health literacy had greater

knowledge about diabetes when compared with participants with limited functional health literacy, $t(377) = 8.338$, $p < .001$.

Oral health literacy and diabetes knowledge. Oral health literacy (as measured by the DM-REALM) was not statistically significantly related to diabetes knowledge, but participants with adequate oral health literacy were more likely to have greater diabetes knowledge when compared with participants with limited oral health literacy, $t(377) = -2.126$, $p < .05$.

Echoing the results of previous studies (Al Sayah et al., 2015; Kim et al., 2004; Mancuso, 2010; Rothman et al., 2005), this study asserts that greater knowledge of diabetes positively and significantly correlates with higher levels of health literacy.

Motivation *(health information-seeking behaviors)*

Functional health literacy and health information-seeking behaviors. Functional health literacy exhibited a significant weak correlation with health information-seeking behaviors, $r = .106$, $p < .05$. Participants with adequate functional health literacy reported more proactive health information-seeking behaviors when compared with participants with limited functional health literacy, $t(379) = 3.203$, $p < .01$.

Oral health literacy and health information-seeking behaviors. Oral health literacy exhibited a significant weak correlation with health information-seeking behaviors, $r = .123$, $p < .05$. No significant differences were identified by oral health literacy level among health information-seeking behaviors.

Very little has been reported in the literature regarding the relationship between health information-seeking behaviors and health literacy among patients with T2DM. This study aids our understanding of this relationship more fully.

***Behavioral skills** (diabetes self-efficacy)*

Functional health literacy and diabetes self-efficacy. Bivariate correlations revealed no statistically significant relationship between functional health literacy and diabetes self-efficacy or a significant difference in diabetes self-efficacy between the two health literacy groups.

Oral health literacy and diabetes self-efficacy. Bivariate correlations revealed no statistically significant relationship between oral health literacy and diabetes self-efficacy or a significant difference in diabetes self-efficacy between the two health literacy groups.

Only one previous study has reported the relationship between diabetes self-efficacy and health literacy in a similar group of patients. Al Sayah et al. (2015) reported that diabetes self-efficacy was significantly and positively correlated with health literacy. The health literacy instrument used in that study, however, was the 3-item Chew HL assessment, which differs considerably from the health literacy instruments in this study.

Diabetes Self-Care Activities and IMB Theoretical Constructs

The primary purpose of this study was to examine the predictors of diabetes SCA in an underserved population with T2DM. In the hierarchical multiple regressions, the predictor variables of the IMB constructs were divided into two groups, matching the

different parts of the model (information and motivation), and hierarchical multiple regressions were used to assess the contribution of each construct.

Information *(health literacy and diabetes knowledge)*

Functional health literacy and diabetes SCA. Functional health literacy was not significantly correlated with diabetes SCA and there were no significant differences in diabetes SCA by functional health literacy score. However, in hierarchical regression analysis, functional HL was identified as a significant predictor of diabetes SCA. In the first step of the multiple regression analysis, functional health literacy and health information-seeking behaviors were found to predict diabetes SCA. The variable added in the second step was motivation (diabetes self-efficacy). It accounted for a significant change in the variance of the outcome variable and diabetes self-efficacy was also found to be a significant predictor of diabetes SCA. Overall, the final regression model accounted for 29% of the variance in diabetes SCA, a medium effect size that provides supports for both information and motivation in predicting diabetes SCA for this underserved population with T2DM.

Oral health literacy and diabetes SCA. Oral health literacy was not significantly correlated with diabetes SCA and there were no significant differences in reported diabetes SCA by oral health literacy score. As outlined before, in the hierarchical multiple regressions, the predictor variables of IMB constructs were divided into two groups, matching the different parts of the model (information and motivation), and hierarchical multiple regressions were used to assess the contribution of each construct. In the first step of the analysis, only health information-seeking behaviors were found to

predict diabetes SCA. Motivation (diabetes self-efficacy), added as a variable in the second step, accounted for a significant change in the variance of the outcome variable; diabetes self-efficacy was a significant predictor of diabetes SCA. Overall, the final regression model accounted for 28% of the variance in diabetes SCA, a medium effect size that provides support for both information and motivation in predicting diabetes SCA for this underserved population with T2DM.

The prevailing literature is inconsistent regarding the relationship between health literacy and diabetes SCA. Most studies have failed to identify a statistically significant direct relationship between health literacy and collective diabetes SCA. Shigaki et al. (2010), who used the same instruments as those in this study, found no correlation between participant scores on the NVS and the summed score of the SDSCA. And although other researchers have sought to identify a relationship between health literacy and summed scores of the SDSCA among patients with T2DM using alternative health literacy instruments, none have established a direct relationship between the two (Al Sayah et al., 2015; Kim et al., 2004; Mancuso et al., 2010; Mbaezue et al., 2010; White et al., 2011). However, correlations between health literacy and specific individual diabetes SCA (as opposed to summative scores of more comprehensive diabetes self-care instruments) have been identified. Two studies that measured health literacy using the REALM identified relationships with foot self-care (McCleary-Jones, 2011) and dietary intake reporting (Bowen et al., 2013). Another, which utilized the S-TOFHLA, identified a relationship with recording of blood glucose tests (Mbaezu et al., 2010); and another

(Brega et al., 2012), using the 3-item Chew HL scale, reported a relationship with both food consumption and self-monitoring of blood glucose.

Motivation *(health information-seeking behaviors)*

Health information-seeking behaviors and diabetes SCA. Health information-seeking behaviors exhibited a significant weak correlation with diabetes SCA, $r = .256$, $p < .01$. Additionally, in the hierarchical regression analyses, health information-seeking behaviors were identified as a significant predictor for diabetes SCA.

Behavioral skills *(diabetes self-efficacy)*

Diabetes self-efficacy and diabetes SCA. Diabetes self-efficacy showed a significant moderate relationship with diabetes SCA, $r = .484$. In the hierarchical regression analyses, diabetes self-efficacy explained a significant amount of the variance in diabetes SCA.

The positive relationship between diabetes self-efficacy and diabetes SCA has been identified before (Cavanaugh et al., 2008) and is a central tenet of the IMB theoretical model – that behavioral skills precede SCA.

Findings Related to Motivation as a Mediator

The findings of the mediation analysis reveal that motivation (health information-seeking behaviors) was a significant mediator of the relationship between information (health literacy) and health behaviors (diabetes SCA). Although health literacy did not have a significant direct effect on diabetes SCA, $b = 0.046$, $p < .132$, health information-seeking behaviors were identified as a mediator in the relationship between oral health literacy and diabetes SCA, $b = 0.015$, 95% CI = 0.001, 0.037.

Recently, studies that have used the IMB model to attempt to explain the effects of information, motivation, and behavioral skills on diabetes SCA have obtained important findings. Two studies have sought to establish behavioral skills as a mediator between health information and diabetes health behaviors. In one, by Alexander et al. (2017), regression analysis revealed a direct relationship between behavioral skills and medication adherence, $b = 0.38$, $p < 0.001$. When all paths were taken into account, behavioral skills significantly mediated the pathway between information and motivation on medication adherence, thus validating the proposed relationships of the theoretical framework. In another recent study exploring diabetes self-management (glycemic control) using the IMB model (Chen et al., 2018), regression analysis established significant direct paths from information to self-management behaviors, $b = 0.119$, $p = 0.001$, from motivation to behavioral skills, $b = 0.670$, $p < 0.001$, and from behavioral skills to self-management behaviors, $b = 0.562$, $p < 0.001$. In a similar study, Mayberry and Osborn (2014) also tested the relationships proposed in the IMB model, using a sample of patients with diabetes. Medication adherence was the self-care activity of interest. Behavioral skills exhibited a direct effect on medication adherence, $b = 0.59$, $p < 0.001$. Mediation analysis revealed that behavioral skills significantly mediated the pathway between information and motivation to medication adherence. None of these studies, however, identified motivation as a significant mediator in the pathway between information and health behaviors, and none incorporated health literacy as an information level variable.

An important contribution of the present study is the finding that although there may not be a direct effect of health literacy on the summed score of the SDSCA, there is an indirect relationship between oral health literacy and diabetes SCA through health information-seeking behaviors.

IMB Theoretical Framework

The IMB theoretical framework is a promising model for studies related to the information, motivation, and behavioral skills necessary to perform diabetes SCA. The mediation analysis in this study has revealed a significant path from health literacy to diabetes SCA through health information-seeking behaviors. Previous studies also assert that the IMB model is an appropriate and comprehensive framework to explain diabetes health behaviors (Chen et al., 2018; Gao et al., 2013; Mayberry & Osborn, 2014: Meunier et al., 2016; Osborn & Egede, 2010; Osborn et al., 2010). In a study by Osborn et al. (2010) that tested the IMB model among Puerto Ricans with T2DM, information and motivation were related to behavioral skills, $r = 0.42$, $p < .01$, and $r = 0.39$, $p < .01$, respectively, and behavioral skills were related to behavior, $r = 0.53$, $p < .001$. Behavior outcomes have ranged from more comprehensive assessments of diabetes SCA, such as the SDSCA (Chen et al., 2018; Gao et al., 2013; Meunier et al., 2016; Osborn & Egede, 2010) to singular diabetes care activities such as diet and exercise behavior (Osborn et al., 2010), self-monitoring of blood glucose (Fisher, Kohut, Schachner & Stenger, 2011), and diabetes medication adherence (Mayberry & Osborn, 2014). Although operationalization of the IMB constructs has differed among studies with similar aims, each study has contributed to a better understanding of the relationships between the information,

motivation and behavioral skills necessary for optimal diabetes self-care. Further research that incorporates this framework will further validate this work.

STUDY STRENGTHS

This study is a secondary analysis of a previous study with notable strengths. The original study included a large diverse sample (n = 388 participants) of underserved patients within an FQHC. As opposed to many previous studies that had collected data from a single clinical site, the principal investigator of the original study recruited participants from six different clinics that were geographically and ethnically diverse. The original study also included only patients with T2DM, which enables clearer inferences about SCA specific to T2DM. Additionally, RAs were fluent in both English and Spanish, and a large percentage of study participants spoke Spanish, unlike in many previous studies that included only English speakers.

This secondary analysis has important strengths: (1) adaptation of the IMB theoretical framework to integrate health literacy as an information level variable; (2) use of two disease-specific health literacy instruments; and (3) robust analysis of health literacy among underserved patients from a Mexico-bordering state.

The IMB theoretical framework has been used to frame studies of patients with diabetes before, but none have integrated health literacy as an information-level variable. Most use diabetes knowledge alone as an assessment of information. Although diabetes knowledge tests are important methods to ascertain what people know about their disease, health literacy can help explain how participants find, process and understand information about their disease. In this study, health literacy was operationalized as a

dynamic construct and was assessed with two different measures. This study will contribute to the growing body of literature concerning operationalization of the variables included in the IMB theoretical framework, integrating health literacy as a cornerstone of information-level variables.

Although there are benefits to using global assessments of health literacy, evidence from this study suggests that disease-specific health literacy instruments may be more appropriate assessments. The NVS utilizes a nutritional label as part of the assessment, the reading of which is a vital skill for patients with diabetes. The results of the NVS can provide important insights about how patients with diabetes find, process, and understand nutritional information. The DM-REALM is a diabetes-specific assessment of oral health literacy. This tool, an adaptation of the original REALM instrument, includes terms commonly used in diabetes self-management. The results of the DM-REALM provide important insights about how comfortable patients are with diabetes self-management language. Disease-specific health literacy instruments offer more robust information about disease self-management skills pertinent to specific populations of patients.

This study has described the health literacy levels of a unique population of patients with diabetes. The majority of participants were undereducated, with very limited socioeconomic resources. Additionally, over one third of participants were Spanish speakers. The findings provide important insights about health literacy among underserved patients with T2DM.

STUDY LIMITATIONS

Findings from this study should be interpreted with care, owing to certain limitations related to data collection, sample biases, self-report instrumentation and generalizability.

Data collection. This study is a secondary analysis of data. Despite notable advantages to secondary analysis, such as time and financial savings, it has inherent limitations. The data were restricted by the questions asked by the original study's authors. Additionally, more variables that might allow better explication of the relationships between information, motivation, behavioral skills, and health behaviors might have added to the study's strength.

Sample Biases. Important biases should be noted when considering this study's results. Participants were selected with convenience sampling; randomization would enhance future studies. Participants were self-selected, and those who showed an eagerness to participate and had the time to complete the survey were able to do so. Social desirability bias may have influenced the way participants answered survey questions, because the surveys were administered within the healthcare clinics where patients received their regular health care.

Self-report Instrumentation. Data were collected from study participants using a self-paced paper survey. Each of the instruments used in the survey was a self-report instrument. The participant's ability to recall important information over the last week, month, or even year was an important factor in the quality of the data.

Generalizability. Participants in this study were primarily poor, undereducated, underinsured, and linguistically diverse. Therefore, limited variability on important variables (HL, education attainment, income) is a critical limitation for generalizability (external validity) of the findings. Future studies that include a more general sample of wide ranges of socioeconomic status are needed to cross-validate these findings and theoretical framework.

STUDY IMPLICATIONS

Implications for Nursing

The findings of this study suggest important implications for the nursing profession. Health literacy is closely related to nursing-specific responsibilities, including patient education, therapeutic communication, and health promotion. All are related to patient engagement. Historically, patient engagement has been viewed as the sole responsibility of the patient, reflecting the patient's motivation to participate in his or her own care. However, this view is evolving, and patient engagement has more recently been described by McCormack et al. (2017) as the product of meaningful relationships between patients, their caregivers or representatives and members of the healthcare team in a partnership to optimize health. The World Health Organization (2016) has called this "the process of building the capacity of patients, families, carers, as well as health care providers, to facilitate and support the active involvement of patients in their own care, in order to enhance safety, quality and people-centeredness of health care service delivery" (p. 3). Nurses are often positioned as the intermediaries between medical practitioners and patients. As healthcare providers who tend to spend the most time with patients,

nurses have the unique opportunity to holistically assess each patient they encounter. Patient engagement depends not only on the patients, but on nurses, as well. Nurses must be familiar with the various methods of assessing health literacy and be sensitive to the unique needs of patients with low health literacy.

It is imperative for nurses to understand the links between low socioeconomic status and health literacy. Although it would be beneficial for every patient to have their level of health literacy assessed by a nurse or another healthcare professional, research has shown that time constraints and limited financial restraints may not make this truly feasible (DeWalt et al., 2011). The vast majority of underserved patients in this study exhibited exceptionally limited functional and oral health literacy. Echoing the results of other studies, many statistically significant relationships were identified between socioeconomic status and level of health literacy. The numerous connections between the two should not be overlooked by the nursing profession. Whether employed by a hospital, community health center, or private practice, nurses have the unique responsibility to assess each patient holistically and consider the social determinants of health when developing a plan for a patient. Nurses should consider the patient's socioeconomic status when determining the most health-literate sensitive way to communicate health information. Some tools have already been developed to assist nurses in providing health-literate care. They include the use of plain language forms, teach back, visual aids, and more. Yet although these tools are available to nurses, underuse or short-term use (primarily due to lack of time) of the tools has been cited in the literature (London, 2016).

In this study, health literacy exhibited an effect on diabetes SCA through health information-seeking behaviors. Motivation played an important role in how patients cared for themselves. It is important that nurses recognize when patients are motivated to learn more about their disease, so that nurses can act on that motivation by providing timely and appropriate information. This information can be communicated orally, through technology (videos, recordings, etc.), or in writing. But these sources must be thoroughly vetted for health literacy appropriateness. As the arbiters of information provided to patients, nurses are uniquely positioned to assess the quality and appropriateness of any information provided to a patient. Nurses cannot be passive extensions of the medical team, but must instead take the role of advocate and ensure that patient education information matches the health literacy skill levels of patients. Nurses in any healthcare environment should be responsible for this task, but for nurses who work regularly with patients at the highest risk of limited health literacy (ethnic minorities, undereducated, with low SES), particularly nurses working in federally qualified health centers, this responsibility is essential.

The literature is unclear as to what extent health literacy is included in nursing undergraduate education. Although the IOM (2004) recommends integrating health literacy into the nursing curriculum, there is no national standard. In a qualitative study by Zanchetta et al. (2013), baccalaureate nursing students benefitted from a curriculum that explicated the interconnectedness between the social determinants of health and health literacy, enhancing their ability to be better health educators. Nursing students are taught extensively about their roles as patient educators, but this training gives very little

attention to the health literacy needs of each patient. However, there is a better consensus regarding the integration of health literacy into the graduate nursing curriculum. In 2012, the Education Consortium within Quality and Safety Education for Nurses (QSEN), a program funded by the RWJ Foundation, created a list of graduate-level QSEN competencies for nursing graduate programs (American Association of Colleges of Nursing, 2012). Included in this list are essential sets of knowledge, skills, and attitudes for graduate level nurses. Health literacy is mentioned three different times: (1) "synthesize critical information about health literacy based on diversity of patient population," (QSEN Knowledge competency); (2) "accept that health literacy is a problem in safe care, especially during the transition to home-based care,"; and (3) "value diversity of health literacy levels among patient populations" (QSEN Attitude competencies). The inclusion of health literacy within a nationally recommended set of standards for the nursing graduate curriculum is promising, but this effort should be applied to the undergraduate curriculum, as well. There is an urgent need for health literacy training for all nurses who provide patient education.

Implications for Health Policy

Until health literacy is explicitly addressed as a public policy priority, very little will change. Currently, no policies address health literacy federally or in the state of Texas. Health literacy is addressed only in population-specific statutes. For example, in an effort to reduce the use of the emergency room for non-emergent reasons by Medicaid recipients, a plan has been proposed by HHSC that allows for funding of programs

related to health literacy (4 Texas Government Code Section 531.085). However, this proposal has not yet been formally adopted.

In Texas, over 4 million people use Medicaid benefits for healthcare (Texas Health & Human Services, n.d.). The Affordable Care Act did permit grants to 10 states as incentives to Medicaid beneficiaries who agreed to participate in prevention programs that demonstrated reduction of health risk as well as positive health outcomes. Texas was chosen as one of the 10 states, and pilot studies are currently underway (CMS, 2018). Through such funding mechanisms, health literacy can be more broadly addressed for people at the highest risk of limited health literacy. Policies related to Medicaid reimbursement that focus on support systems in place for patients with limited health literacy or programs to enhance health literacy could have a profound impact on patient care.

Healthcare centers that serve the underserved (high recipients of Medicaid benefits) should implement health literacy in all patient support systems, including written, visual, and oral communication. Funding should be contingent on health-literate practices.

Implications for Healthcare Systems

As evidence from this study suggests, healthcare systems, and more specifically, federally qualified health centers may have disproportionately more patients with limited health literacy. Healthcare systems cannot overlook an issue that is so widespread among patients. The issue of limited health literacy highlights the opportunity for healthcare systems to review all of the support systems in place for patients including patient-

provider communication, patient education, case management, and patient counseling, and assess each for congruence with a limited health literacy level.

The high prevalence of limited health literacy in this study population reinforces the need for healthcare systems to address this issue at a systems level. Over the last 10 years, several toolkits have been developed to help practices address health literacy at a systems level. For example, the Agency for Healthcare Research and Quality has published the Health Literacy Universal Precautions Toolkit (De Walt et al., 2011) to guide improvements within primary care practices. This toolkit identifies four key practice areas for promoting health literacy: (1) spoken communication, (2) written communication, (3) patient self-management & empowerment and (4) supportive systems for patients. At over 200 pages, the toolkit is comprehensive. However, due to its age, it may require significant updating.

The National Action Plan to Improve Health Literacy was developed by the Office of Disease Prevention and Health Promotion within the U.S. Department of Health and Human Services in 2010. This report outlines seven goals for improving health literacy in order to advance public health in the United States. The goals are comprehensive, specifically addressing how healthcare systems should focus on health-literate communication, written information, shared decision-making and access for the patients they serve.

A roundtable discussion about Health Literacy at the Institute of Medicine in 2012 (now named the Health and Medicine Division of the National Academies) resulted in a report titled *Ten Attributes of Health Literate Health Care Organizations* (Brach et al.,

2012). This report outlines 10 ways in which healthcare systems can integrate health literacy into their practices to aid all patients in the navigation of healthcare services.

As supported by Koh et al. (2013), healthcare systems could adopt a universal approach to health literacy by reducing the health literacy burden on every patient in their system. Using a systems approach, all opportunities to interact with the patients – from oral to written communication – should be redesigned with the limited health-literate user in mind.

However, recommendations are not enough. The findings of this study highlight the important role healthcare systems have in providing care that is more sensitive to health literacy levels. First, (as suggested by Koh et al., 2013), healthcare systems can elevate health literacy as an important consideration for every service provided to patients. Second, as evidenced by the high prevalence of limited health literacy among Spanish speakers in this study, healthcare systems can provide additional supports for Spanish-speaking patients. Third, healthcare systems should consider the support systems in place for educating patients with T2DM. Participants in this study found it very difficult to find and interpret the information presented on a nutrition label. This skill is vitally important for patients with T2DM. Healthcare systems should ensure that diabetes self-management classes and training provided to patients with T2DM explicitly include instructions about using nutrition labels.

Implications for Future Research

The findings of this study suggest several important implications for future research. To further validate this study's findings and others like them, consistent use of

the same theoretical framework would be helpful. The information-motivation-behavioral skills theoretical framework (Fisher & Fisher, 1992) shows great promise for health literacy and diabetes health behavior research. Additionally, the use of disease-specific health literacy instruments, such as the DM-REALM and the NVS provided important insights about this population of patients. However, the non-normal distribution of the NVS data suggests that a more heterogeneous sample of participants should be recruited for future studies.

This study revealed that health information-seeking behaviors (motivation) was an important mediator in the relationship between health literacy (information) and diabetes SCA (health outcome). Future intervention studies aimed at improving self-care or self-management should incorporate patient motivation as a variable linking health literacy and SCA.

The health literacy social ecological model proposed by McCormack et al. (2017) illustrates how health literacy skills and patient engagement are complementary. The authors suggest that future interventions to enhance health literacy should be addressed at individual and systems levels, which will result in positive impacts on patient engagement. In alignment with the "universal approach" to health literacy, but also in support of interventions aimed at improving individual health literacy, this model shows great promise for future health literacy intervention research.

CONCLUSION

People with low health literacy are at higher risk of complications related to their health (Berkman et al., 2011). Those with limited resources are disproportionately

affected by low health literacy (Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, 1999; Easton et al., 2010). The findings of this study support both of these important points. This study has shown that limited health literacy among underserved patients with T2DM is pervasive and that it elicits an indirect effect on diabetes SCA. In addition, health information-seeking behaviors have a mediating effect on the relationship between health literacy and diabetes SCA. Future research is needed to elicit more evidence regarding pathways from health literacy to diabetes SCA. This study has suggested clear implications for nursing, healthcare systems, health policy and future research.

Appendices

APPENDIX A: IRB APPROVAL LETTER AND APPROVED DOCUMENTS

A-1: IRB Approval Letter for the Original Study

OFFICE OF RESEARCH SUPPORT

THE UNIVERSITY OF TEXAS AT AUSTIN

P.O. Box 7426, Austin, Texas 78713 · Mail Code A3200
(512) 471-8871 · FAX (512) 471-8873

FWA # 00002030

Date: 03/20/15

PI: Miyong Kim

Dept: Nursing

Title: Assessment of Health Literacy for Low-Income Patients in Travis County, Texas

Re: IRB Expedited Approval for Protocol Number 2014-10-0073

Dear Miyong Kim:

In accordance with the Federal Regulations the Institutional Review Board (IRB) reviewed the above referenced research study and found it met the requirements for approval under the Expedited category noted below for the following period of time: 03/20/2015 to 03/19/2016 . *Expires 12 a.m. [midnight] of this date*. If the research will be conducted at more than one site, you may initiate research at any site from which you have a letter granting you permission to conduct the research. You should retain a copy of the letter in your files.

Expedited category of approval:

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review). (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children2, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ 3) Prospective collection of biological specimens for research purposes by non-invasive means. Examples:
- (a) Hair and nail clippings in a non-disfiguring manner.
- (b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- (c) Permanent teeth if routine patient care indicates a need for extraction.

(d) Excreta and external secretions (including sweat).
(e) Uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue.
(f) Placenta removed at delivery.
(g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor.
(h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
(i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.
(j) Sputum collected after saline mist nebulization.

☐ 4) Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).
Examples:
(a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy.
(b) Weighing or testing sensory acuity.
(c) Magnetic resonance imaging.
(d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.
(e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☒ 5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

☐ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☒ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

☒ Use the attached approved informed consent document(s).

☐ You have been granted a Waiver of Documentation of Consent according to 45 CFR 46.117 and/or 21 CFR 56.109(c)(1).

☐ You have been granted a Waiver of Informed Consent according to 45 CFR 46.116(d).

Responsibilities of the Principal Investigator:

1. Report immediately to the IRB any unanticipated problems.

2. Submit for review and approval by the IRB all modifications to the protocol or consent form(s). Ensure the proposed changes in the approved research are not applied without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject. Changes in approved research implemented without IRB review and approval initiated to eliminate apparent immediate hazards to the subject must be promptly reported to the IRB, and will be reviewed under the unanticipated problems policy to determine whether the change was consistent with ensuring the subjects continued welfare.

3. Report any significant findings that become known in the course of the research that might affect the willingness of subjects to continue to participate.

4. Ensure that only persons formally approved by the IRB enroll subjects.

5. Use only a currently approved consent form, if applicable.
   Note: Approval periods are for 12 months or less.

6. Protect the confidentiality of all persons and personally identifiable data, and train your staff and collaborators on policies and procedures for ensuring the privacy and confidentiality of subjects and their information.

7. Submit a Continuing Review Application for continuing review by the IRB. Federal regulations require IRB review of on-going projects no less than once a year a reminder letter will be sent to you two months before your expiration date. If a reminder is not received from Office of Research Support (ORS) about your upcoming continuing review, it is still the primary responsibility of the Principal Investigator not to conduct research activities on or after the expiration date. The Continuing Review Application must be submitted, reviewed and approved, before the expiration date.

8. Upon completion of the research study, a Closure Report must be submitted to the ORS.

9. Include the IRB study number on all future correspondence relating to this protocol.

If you have any questions contact the ORS by phone at (512) 471-8871 or via e-mail at orsc@uts.cc.utexas.edu.

Sincerely,

James P. Wilson

James Wilson, Ph.D.
Institutional Review Board Chair

A-2: Consent for Participation in Research – English

Consent for Participation in Research

Title: Diabetes Health Literacy Patient Survey

Introduction

The purpose of this form is to provide you with information that may affect your decision as to whether or not to participate in this research study. The person performing the research will answer any of your questions. Read the information below and ask any questions you might have before deciding whether or not to take part. If you decide to be involved in this study, this form will be used to record your consent.

Purpose of the Study

You have been asked to participate in a research study about **an assessment of health literacy**. The purpose of this study is **to identify the level of health literacy of patients with type II diabetes.**

What will you be asked to do?

If you agree to participate in this study, you will be asked to

- **Sign the consent form and a HIPAA Authorization Form**
- **Fill out a short demographic survey**
- **Complete 3 health literacy scales**
- **Complete questionnaires about your diabetes specific questions, mental health, and health services**
- **Allow our research team to access your health records and record the information detailed in the HIPAA Authorization Form**

This study will take about **30 minutes to complete** and will include approximately **1,000** study participants.

What are the risks involved in this study?

There are no foreseeable risks to participating in this study. The study poses minimal physical, psychological, social, legal, or other risks to the participants.

What are the possible benefits of this study?

You will receive no direct benefit from participating in this study; however, **the information you provide today will help others with chronic illness and their utilization of health services.**

Do you have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with The University of Texas at Austin (University) or CommUnityCare in anyway.

If you would like to participate, you may accept the provisions in the form and agree to join this study. You will receive a copy of this form.

Will there be any compensation?

You will receive a $10 HEB Gift Card. Payments will occur directly after the survey.

How will your privacy and confidentiality be protected if you participate in this research study?

Your privacy and the confidentiality of your data will be protected by the assignment of a confidential study identification number so that your name will not appear on any data collection form. Again, all research data will be obtained strictly for research purposes. Data will be entered into a computerized password-protected database by study numbers only. Only the investigators who require the use of data for analysis will have access to the study data; otherwise the data will not be shared with anyone, including those affiliated with the research. After completion of the study, all names will be deleted, and the data will be identifiable only by a study number. Health status data will be offered to participants and to their physicians only with participant consent. The investigative team is keenly aware of the need to protect participant confidentiality, as well as corresponding legal requirements, including those mandated by HIPAA (the Health Insurance Portability and Accountability Act). All electronic data collection and storage will be password-protected and saved in a secure fashion. All study-related computers will be under firewall protection and will maintain automated virus update mechanisms. Timely notification regarding relevant patches will be provided. Hard copies of the data collection forms will be store in locked cabinets or areas. Only authorized personnel will have access to these locked areas. In addition, all study staff will sign a confidentiality statement annually attesting to their understanding of, and willingness to abide by, the written policies for staff regarding research ethics and confidentiality. Access to the data entry website will be password-protected and restricted to personnel trained to use the system. The participants' identifiable data will be destroyed three years after analysis is complete.

If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with you, or with your participation in any study.

Whom to contact with questions about the study?

Prior, during or after your participation you can contact the researcher **Dr. Miyong Kim at 512-471-8361** or send an email to **mkim@nursing.utexas.edu** for any questions or if you feel that you have been harmed.

Whom to contact with questions concerning your rights as a research participant?

For questions about your rights or any dissatisfaction with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 471-8871 or email at orsc@uts.cc.utexas.edu.

Participation

If you agree to participate, you will read the consent form and sign your printed name and signature. We will give you a copy of this signed and dated consent form.

Signature

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____
Printed Name

_____ _____
Signature Date

As a representative of this study, I have explained the purpose, procedures, benefits, and the risks involved in this research study.

_____
Print Name of Person obtaining consent

_____ _____
Signature of Person obtaining consent Date

A-3: Consent for Participation in Research – Spanish

SOLO PARA USO DE IRB
Número de Investigación: 2014-10-0073
Fecha de Aprobación: 06/19/2015
Fecha de Vencimiento: 03/19/2016

Consentimiento para participación en investigación

Titulo: Encuesta de alfabetismo de pacientes con Diabetes.

Introducción

El objetivo de esta forma es proveerle información que puede afectar su decisión en cuanto a si participar en este estudio de investigación. La persona que realiza la investigación responderá a cualquier pregunta. Lea la siguiente información y preguntar cualquier duda que tengas antes de decidir si participar o no. Si usted decide participar en este estudio, se utilizará este formulario para registrar su consentimiento.

Objetivo del studio

Le han pedido participar en un estudio de investigación sobre la evaluación de la salud. El propósito de este estudio es identificar el nivel de alfabetización de la salud de los pacientes con diabetes tipo 2.

¿ Lo que se pedirá hacer?

Si consiente en participar en este estudio, preguntarán a usted

- **Firmar el formulario de consentimiento y el Formulario de Autorización de HIPAA**
- **Llene una encuesta demográfica**
- **Completar las escalas de salud alfabetización**
- **Completar los cuestionarios sobre la salud mental, la calidad de vida y los servicios de salud**
- **Permitir que nuestro equipo de investigación para acceder a sus registros de salud y registrar la información detallada en el Formulario de Autorización de HIPAA**

Este estudio durará unos 30 minutos para completar los cuestionarios y contará con aproximadamente 1.000 participantes.

¿Cuáles son los riesgos involucrados en este estudio?

No hay riesgos previsibles a participar en este estudio. El estudio plantea un mínimo bienestar físico, psicológico, social, legal, u otros riesgos para los participantes.

¿Cuáles son las posibles ventajas de este estudio?

Usted no recibirá ningún beneficio directo de participar en este estudio; Sin embargo, la información que usted proporciona hoy ayudará a otras madres en el futuro en sus prácticas de crianza de los hijos y la utilización de los servicios de salud.

¿Tienes que participar?

No, su participación es voluntaria. Usted puede decidir no participar en absoluto o, si se inicia el estudio, usted podrá retirar en cualquier momento. Retirada o negarse a participar no afectan su relación con la Universidad de Texas en Austin (Universidad) de todos modos.

Si le gustaría participar, **puede aceptar las provisiones en la forma y consentir en afiliarse a este estudio.** Usted recibirá una copia de este formulario.

¿Habrá alguna compensación?

Usted recibirá una **$10 HEB tarjeta**. Los pagos se producirán **Proporcionar directamente después de la encuesta.**

¿Cómo va la confidencialidad y la privacidad de nuestros clientes ser protegidos si participa en el estudio de investigación?

Su privacidad y la confidencialidad de sus datos estará protegidas por ser asignado a un número de identificación del estudio confidencial para que nombres no aparecerán en cualquier formulario de recogida de datos. Una vez más, se obtiene todos los datos de investigación estrictamente para fines de investigación. Datos serán incorporados a una base de datos informatizada protegido con contraseña por estudio sólo números. Sólo los investigadores que requieren el uso de datos para análisis tendrá acceso a los datos del estudio; de lo contrario los datos no se compartirá con nadie, incluyendo a los afiliados con la investigación. Después de la terminación del estudio, se eliminarán todos los nombres y los datos serán identificables sólo por un número de estudio. Datos de estado de salud se ofrecerá a los participantes y a sus médicos sólo con el consentimiento de participante. El equipo de investigación está muy consciente de la necesidad de proteger la confidencialidad participante, así como los requisitos legales correspondientes, incluyendo aquellos establecidos por HIPAA (Health Insurance Portability y Accountability Act). Todos los datos electrónicos de recolección y almacenamiento serán protegido con contraseña y guardados en forma segura. Todos los equipos relacionados con el estudio estarán bajo la protección de firewall y mantendrán los mecanismos de actualización automatizada de virus. Se proporcionará notificación oportuna sobre parches relevantes. Copias de los formularios de recogida de datos serán tienda en gabinetes con llave o áreas. Sólo el personal autorizado tendrá acceso a estas áreas cerradas. Además, todo el personal de estudio firmarán una declaración de confidencialidad anualmente atestiguando su entendimiento y voluntad de acatar, las políticas escritas para el personal con respecto a la ética de la investigación y la confidencialidad. Acceso a la página de entrada de datos estará protegido con contraseña y restringida a personal capacitado para utilizar el sistema. Datos personales de los participantes serán destruidos tres años después de que termine el análisis.

Si llega a ser necesario que la Junta de Revisión Institucional (IRB) revise los registros del estudio, la información que pueda ser ligada a usted será protegida hasta la medida permitida por la ley. Sus registros del estudio no serán divulgados sin su permiso almenos que sea requerido por ley o por un mandato judicial. Los datos que resulten de su participación pueden ser usados por otros investigadores en el futuro para proyectos de investigación no detallados dentro de esta forma de consentimiento. En estos casos, los datos no contendrán información de identificación que se pueda asociar con su hijo/a, o con su participación en cualquier estudio.

¿Quien entre en contacto con preguntas sobre el estudio?

Antes, durante o después de su participación puede contactar con el investigadora **Dr. Miyong Kim at 512-471-8361** o envíe un correo electrónico a mkim@nursing.utexas.edu para cualquier pregunta o si siente que ha sido dañado.

¿Quien entre en contacto con preguntas acerca de sus derechos como participante de investigación?

Para preguntas acerca de sus derechos o cualquier insatisfacción con cualquier parte de este estudio, puede contactar, anónimamente si lo desea, la Junta de revisión institucional por teléfono (512) 471-8871 o envíe un correo electrónico a orsc@uts.cc.utexas.edu.

Participación

Si usted acepta participar, leerá el formulario de consentimiento y firmar su nombre y firma. Le daremos una copia de este formulario de consentimiento firmado y fechado.

Firma

Ha sido informado sobre objetivo de este estudio, procedimientos, ventajas posibles y riesgos, y ha recibido una copia de esta forma. Le han dado la oportunidad de hacer preguntas antes de que firme, y le han dicho que puede hacer otras preguntas en cualquier momento. Voluntariamente consiente en participar en este estudio. Firmando esta forma, no renuncia ninguno de sus derechos legales.

_____
Nombre de la letra

_____ _____
Firma Fecha

Como representante de este estudio, he explicado el propósito, procedimientos, beneficios y los riesgos involucrados en este estudio de investigación.

_____
Nombre de la letra de Persona que obtiene consentimiento

_____ _____
Firma de Persona que obtiene consentimiento Fecha

A-4: HIPAA Research Authorization – English

HIPAA Research Authorization

Authorization for the Creation, Use and Disclosure of Protected Health Information for Institutional Review Board Approved Research.

[Instructions: This authorization should be attached to the Consent to Participation in Research form. Principal investigators must complete information fields below and questions 8, 9. Leave subject name and signature areas blank to be completed by research subject.]

Title of Study:	Diabetes Health Literacy Patient Survey
Name of Investigator:	Miyong Kim
Email Address	mkim@nursing.utexas.edu
Phone Number:	(512) 471-8361
IRB Number:	2014-10-0073
Protocol Approval Date:	03/20/2015
Consent Form Approval Date:	03/20/2015

This authorization is voluntary and you may refuse to sign this authorization. If you refuse to sign this authorization, your health care and relationship with The University of Texas at Austin (University) will not be affected. However, you will not be able to enter this research study.

1. This form authorizes the University to use and disclose (release) certain protected health information (PHI) about (Name of Subject): _____

   that we will collect and create in this research study. The description of the information to be used or disclosed and the purposes of the requested use or disclosure are indicated in item number 8 of this form.

2. The persons who are authorized to use and disclose your PHI are:

   - ☒ All investigators listed on the Consent to Participation in Research form and others at the University who are participating in the conduct of the research protocol.
   - ☒ The University's Institution Review Board.
   - ☐ Others:

3. The persons who are authorized to receive this information are:

   - ☐ The sponsor of this study:
   - ☐ Federal or other government agencies as required for their research oversight and public health reporting in connection with this study.
     - ☐ The Office of Human Research Protections (OHRP)
     - ☐ U.S. Food and Drug Administration (FDA)
     - ☐ The National Institutes of Health (NIH)
     - ☐ Other:

4. We may continue to use and disclose PHI that we collect from you in this study until:

   - ☐ The Health Insurance Portability and Accountability Act (HIPAA) Research Authorization expires. Expiration Date:
   - ☒ The study is completed. Completion Date: Three years after the analysis is complete
   - ☐ Indefinitely
   - ☐ Other:

5. While this study is still in progress, you may not be given access to medical information about you that is related to the study until after the research is complete. After the study is completed and the results have been analyzed, you will be permitted access to any medical information collected about you in the study that is maintained in your medical record.

6. You may withdraw, at any time, your permission to provide this information to the researchers. However, once this information has been shared with the researchers, the information will be in their possession. To withdraw your permission, you will need to take one of the following courses of action:
   a. If your information has already been given to the researchers, you should send a written and dated notice of this decision to the principal investigator of this research study at the email address listed above. Upon receipt of this request, the researchers will destroy your information that was provided to them.
   b. If your information has NOT already been given to the researchers, you should contact by telephone your doctor or a member of your doctor's health care staff. With receipt of this request, your information will not be shared with the researchers.

   You decision to withdraw your permission to provide this information to the researchers will have no effect on your current or future medical care or your relationship with the University, your doctor or health care provider.

7. The information about you that is used or disclosed in this study may be re-disclosed and no longer protected under federal law.

8. Description of the information to be used or disclosed and the purposes of the requested use of disclosure:

Health Information

☒ Limited information from your existing health record which includes:
1) Age, birth date, gender, ethnicity 2) Medical information: list of diagnoses, diabetes medications, clinical outcomes for DM (HbA1c, Lipid level, blood pressure, height, and weight) 3) Insurance information

The following checked items will be generated/collected during the course of this study:

☐ History and physical examinations
Reports: ☐ Laboratory ☐ Surgical ☐ Discharge ☐ Progress
☐ Photographs, videos, digital or other images
☐ Diagnostics images/X-ray/MRI/CT
☐ Bioelectric Output (e.g., EEG, EKG)
☐ Questionnaires, interview results, focus group survey, psychology survey, behavioral tests (e.g., memory and attention)
☐ Tissue and/or blood specimens
☐ Other:

Purpose

☐ Learn more about the condition/disease being studied.
☐ Facilitate treatment, payment, and operations related to the study.
☐ Comply with federal or other government agency regulations.
☐ Teaching or instructional.
☐ To place in a repository or information/tissue bank.
☒ Other: Investigate influencing factors on health literacy

You will receive a copy of this authorization from after it has been signed.

_____
Printed Name

_____ _____
Signature Date

_____
Print Name of Person obtaining consent

_____ _____
Signature of Person obtaining consent Date

A-5: HIPAA Research Authorization – Spanish

HIPAA Autorización de Investigación

Autorización para la Creación, Uso y Divulgación de Información de Salud Protegida para la Junta de Revisión Institucional Aprobó la Investigación.

[Instrucciones: Esta autorización debe sujetarse a la autorización para la participación en forma de investigación. Investigadores principales deben completar campos de información abajo y preguntas 8, 9. Licencia nombre y firma de áreas temáticas en blanco debe ser completado por el tema de investigación.]

Título de estudio:	Assessment of Health Literacy for Low-Income Patients Travis County, Texas
Nombre del investigador:	Miyong Kim
Dirección de correo electrónico	mkim@nursing.utexas.edu
Número de teléfono:	(512) 471-8361
Número de IRB:	2015-10-0073
Fecha de aprobación Protocolo:	03/20/2015
Fecha de aprobación de formulario de consentimiento:	03/20/2015

Esta autorización es voluntaria y usted puede negarse a firmar esta autorización. Si se niega a firmar esta autorización, su salud y su relación con la Universidad de Texas en Austin (Universidad) no serán afectados. Sin embargo, usted no será capaz de entrar en este estudio de investigación.

1. Este formulario autoriza a la Universidad para utilizar y revelar (comunicado) ciertos protección la información de la salud (PHI) sobre (Nombre de sujeto):_____

   que nos recogerá y crear en este estudio de investigación. La descripción de la información a ser usada o divulgada y los propósitos de la uso solicitada o la divulgación están indicados en el artículo número 8 de esta forma.

2. Las personas que están autorizadas a usar y revelar su PHI son:

   ☒ Todos los investigadores mencionados en el consentimiento a la participación en forma de investigación y otros en la Universidad que están participando en la realización del Protocolo de investigación.
   ☒ Junta de revisión de institución de la Universidad.
   ☐ Otros:

3. Las personas que están autorizadas a recibir esta información son:

   ☐ El patrocinador de este estudio:
   ☐ Federal o otras agencias del gobierno como lo exige su investigación supervisión y presentación de informes en relación con este estudio de la salud pública.
   ☐ La Oficina de Protección sobre la investigación en humanos (OHRP)
   ☐ Administración de Drogas y Alimentos de ESTADOS UNIDOS (FDA)
   ☐ Los Institutos Nacionales de la Salud (NIH)
   ☐ Otro:

4. Podemos continuar a utilizar y divulgar su PHI que obtenemos de usted en este estudio hasta:
   - ☐ El Acto de Responsabilidad y Portabilidad de Seguro médico (HIPAA) Autorización de Investigación expira. Fecha de caducidad:
   - ☒ El estudio se completa. Fecha de terminación: Tres años después de completar el análisis
   - ☐ Indefinidamente
   - ☐ Otro:
5. Mientras este estudio todavía está en el progreso, le pueden no dar el acceso a la información médica sobre usted que está relacionada con el estudio hasta que la investigación sea completa. Después de que el estudio es completado y los resultados han sido analizados, le permitirán el acceso a cualquier información médica coleccionada sobre usted en el estudio que es mantenido en su registro médico.

6. Usted podrá retirar, en cualquier momento, su permiso para proporcionar esta información a los investigadores. Sin embargo, una vez que esta información ha sido compartida con los investigadores, la información se presentará en su posesión. Para retirar su permiso, tendrá que tomar uno de los siguientes cursos de acción:
   a. Si su información ya ha sido dado a los investigadores, usted debe mandar un aviso escrito y fechado de esta decisión a la investigadora principal de este estudio de investigación en la dirección de correo electrónico mencionada anteriormente. Al recibir esta petición, los investigadores va a destruir la información que fue proporcionada a ellos.
   b. Si su información no se ha dado ya a los investigadores, debe contactar por teléfono a su médico o a un miembro del personal de atención médica de su médico. Con el recibo de esta solicitud, su información no se compartirá con los investigadores.

   Su decisión de retirar su permiso para proporcionar esta información a los investigadores no tendrá efecto sobre su atención médica actual o futuro o su relación con la Universidad, su médico o proveedor de atención médica.

7. La información sobre usted que es usada o divulgada en este estudio puede volver a divulgarse y ya no tiene protección bajo la ley federal.

8. Descripción de la información a ser usada o divulgada y los propósitos del uso requerido de divulgación:

   Información de salud

   - ☒ Información limitada de su registro de salud que incluye:
     1) Edad, fecha de nacimiento, sexo, etnia 2) información médica: lista de diagnósticos, medicamentos para la diabetes, los resultados clínicos para DM (HbA1c, niveles de los lípidos, la presión sanguínea, la altura y el peso) 3) información de Seguros

   Los siguientes elementos seleccionados serán generados/recogida en el curso de este estudio:

   - ☐ Historia y exámenes físicos
     Informe: ☐ laboratorio ☐ Quirúrgico ☐ Alta ☐ Progresso
   - ☐ Fotografías, vídeos, digital u otras imágenes
   - ☐ Diagnostics images/X-ray/MRI/CT
   - ☐ Salida de energía bioeléctrica (e.g., EEG, EKG)
   - ☐ Cuestionarios, entrevista resultados, encuesta focus group, estudio psicología, Análisis conductual (e.g., memoria y atención)
   - ☐ Tejido y/o muestras de sangre
   - ☐ Otro: Edad, fecha de nacimiento, sexo, estado civil, preferencia de idioma, origen étnico, educación 2) información médica: historia relevante, la diabetes, los resultados clínicos para DM (HbA1c, niveles de los lípidos, la presión sanguínea, la altura y el peso) 3) información de Seguros.

Objeto

- ☐ Aprenda más acerca de la condición/enfermedad estudiada.
- ☐ Facilitar el tratamiento, pago y operaciones relacionadas con el estudio.
- ☐ Cumplir con la ley federal u otro organismo gubernamental reglamentos.
- ☐ Enseñanza o instrucción.
- ☐ Para colocar en un repositorio o información/banco de tejidos.
- ☒ Other: Investigar los factores que influyen en la educación de la salud maternal.

Usted recibirá una copia de esta autorización después de que ha sido firmado.

_____
Nombre impreso

_____ _____
Firma Fecha

_____
Nombre de la letra de persona que obtiene consentimiento

_____ _____
Firma de persona que obtiene consentimiento Fecha

A-6: IRB Exemption notification for this study (secondary analysis of data).

OFFICE OF RESEARCH SUPPORT & COMPLIANCE

THE UNIVERSITY OF TEXAS AT AUSTIN

P.O. Box 7426, Austin, Texas 78713 · Mail Code A3200
(512) 471-8871 · FAX (512) 471-8873

FWA # 00002030

Date: 05/16/2018
PI: Miyong Kim
Dept: Nursing
Title: The Impact of Health Literacy on Self-Care Activities Among Patients with Type 2 Diabetes

Re: Non-Human Subjects Research Determination

Dear Miyong Kim,

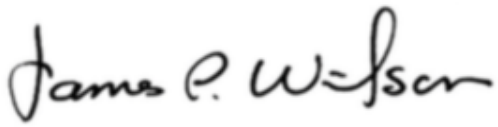
The Office of Research Support & Compliance (RSC) reviewed the above protocol submission request and determined it did not meet the criteria for human subjects research as defined in the Common Rule (45 CFR 46) or FDA Regulations (21 CFR 56). IRB review and oversight is not required because the activities involve:

- ☐ No human interactions
- ☐ Classroom activities used to teach methodology and technique
- ☐ Program evaluation where results are not generalized to other services or programs
- ☑ Secondary use of de-identified data set (no direct or links to identifiers)
- ☐ Obtaining information that is not about living individuals
- ☐ Obtaining information from publicly available sets
- ☐ Biographical research that is not generalizable beyond the individual
- ☐ Archival research using existing literature
- ☐ Other (Explain):

At this time you are free to begin your research as IRB approval is not necessary. You should retain this letter with the respective research documents as evidence that IRB review and oversight is not required.

If you have any questions contact the RSC by phone at (512) 471-8871 or via e-mail at orsc@uts.cc.utexas.edu

Sincerely,



James Wilson, Ph.D.
Institutional Review Board Chair

APPENDIX B: LETTER OF SUPPORT FROM COMMUNITYCARE

Administrative Offices
15 Waller Street, 5th Floor
512-978-9000

A.K. Black
926 Blackson Avenue
512-978-9740

ARCH Homeless Clinic
500 E. 7th Street
(At the ARCH)
512-978-9920

Ben White Dental
1221 W. Ben White #112B
512-978-9700

Children's Wellness Center
UT School of Nursing
5301 Ross Road #H
512-386-3335

David Powell
4614 North IH-35
512-978-9100

Del Valle
3518 FM 973
512-978-9760

East Austin
211 Comal Street
512-978-9200

Family Wellness Center
UT School of Nursing
2901 North IH-35, #101
512-232-3900

Manor
600 W. Carrie-Manor
512-978-9780

Montopolis
1200-B Montopolis
512-978-9800

Northeast Austin
7112 Ed Bluestein
512-978-9300 Dental
512-978-9880

Oak Hill
8656-A Hwy 71
512-978-9820

Pflugerville
15288 Foothill Farm Loop
512-978-9840

RBJ Dental Clinic
15 Waller Street
512-978-9895

Red River
1215 Red River
(Inside Health South)
512-978-9940

Rosewood Zaragosa
2802 Webberville Road
512-978-9400

Rundberg
825 E. Rundberg
512-978-9600

South Austin
2529 S. First Street
512-978-9500 Dental
512-978-9865

William Cannon
6801 IH-35
512-978-9960

Women's Health
1313 Red River #320
512-978-8870

CommUnityCare

Federally Qualified Health Centers • Joint Commission Accredited

December 19, 2014

Dr. James Wilson, Ph.D.
Chair, Institutional Review Board
P.O. Box 7426
Austin, TX 78713
irbchair@austin.utexas.edu

Dear Dr. Wilson:

The purpose of this letter is to grant Miyong Kim, a professor at the University of Texas at Austin permission to conduct research at CommUnityCare (CUC), a Federally Qualified Health Center system serving Travis County, Texas. The project, "Assessment of Health Literacy for Low-Income Patients in Travis County, Texas" entails providing facilities for recruiting participants and data collection. About 1,000 participants will be assessed from 6 sites that were selected as the health center sites serve patients that have the most representative demographic characteristics. CUC was selected because they have 25 sites and provide over 220,000 medical and dental appointments each year to more than 68,000 Travis County residents whose incomes and lack of private health insurance quality them for enrollment.

I, Terri Sabella, Chief Operating Officer of CUC, am included in the proposal and as a primary community partner organization, CUC will share the programmatic and managerial responsibility with the investigators. I do hereby grant permission for Miyong Kim to conduct Assessment of Health Literacy for Low-Income Patients in Travis County, Texas at CommUnityCare Health Center.

Sincerely,

Terri Sabella RN JD
Chief Operating Officer
CommUnityCare
2115 Kramer
Austin, TX 78758
Office: (512) 978-8460

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APPENDIX C: INSTRUMENTS

C-1: NEWEST VITAL SIGN (NVS)

NEWEST VITAL SIGN

⊙ *READ TO SUBJECT: This information is on the back of a container of a pint of ice cream.*

1. If you eat the entire container, how many calories will you eat?
   Si se come todo el contenedor, ¿cuántas calorías habrá consumido?

   _____

2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have?
   Si usted puede consumir 60 gramos de carbohidratos, ¿cuanto de este helado puede comer?

   _____

3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?
   Su médico le recomienda que usted reducir las grasas saturadas en su dieta. Usted normalmente consume 42 gramos de grasa saturada al día, incluyendo una porción de helado. Si deja de comer helado, ¿cuántos gramos de grasa saturada consumiría cada día?

   _____

4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?
   Si usted normalmente consume 2,500 calorías/dia, ¿Qué por ciento de su calorías diairas comeria si come una porción?

   _____

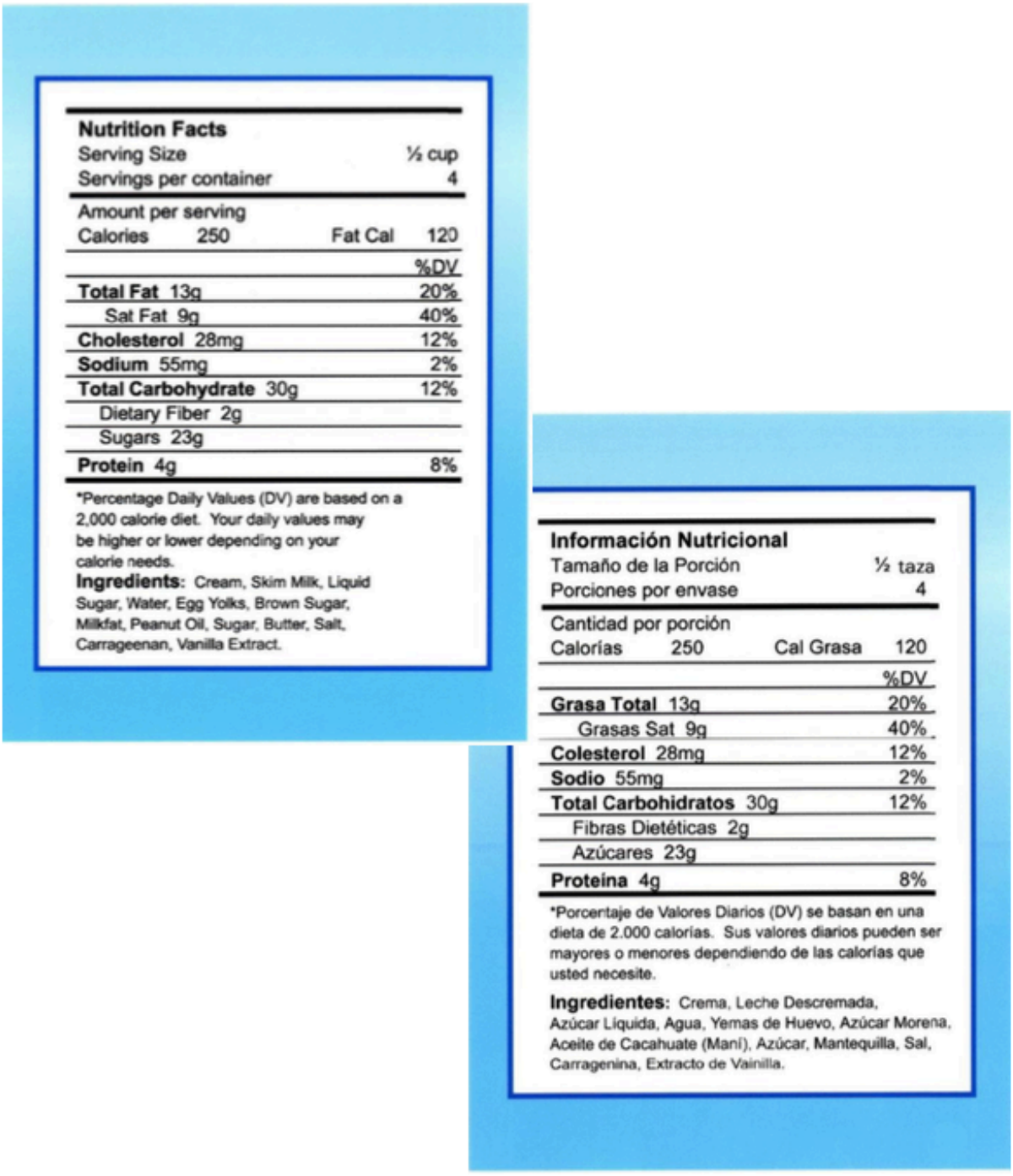
⊙ *READ TO SUBJECT: Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.* ***Finja que eres alérgico a las sustancias siguientes: penicilina, cacahuetes, guantes del látex y picaduras de abeja.***

5. Is it safe for you to eat this ice cream?
   ¿Puede comer este halado con seguridad?

   O YES/***Si*** O NO

6. (Ask only if the patient responds "no" to question 5): Why not?
   Por que no?

   _____



Nutrition Facts

Serving Size	½ cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

Información Nutricional

Tamaño de la Porción	½ taza
Porciones por envase	4
Cantidad por porción	
Calorías 250	Cal Grasa 120
	%DV
Grasa Total 13g	20%
Grasas Sat 9g	40%
Colesterol 28mg	12%
Sodio 55mg	2%
Total Carbohidratos 30g	12%
Fibras Dietéticas 2g	
Azúcares 23g	
Proteína 4g	8%

*Porcentaje de Valores Diarios (DV) se basan en una dieta de 2.000 calorías. Sus valores diarios pueden ser mayores o menores dependiendo de las calorías que usted necesite.

Ingredientes: Crema, Leche Descremada, Azúcar Líquida, Agua, Yemas de Huevo, Azúcar Morena, Aceite de Cacahuate (Maní), Azúcar, Mantequilla, Sal, Carragenina, Extracto de Vainilla.

C-2: DM-REALM

List 1		List 2		List 3	
Pill/ **Pastilla**	O	Dizzy/ **Mareada**	O	Glaucoma	O
Eye/ **Ojo**	O	Fatigue/ **Cansancio**	O	Circulation/ **Circulacion**	O
Fat/ **Grasa**	O	Exchange/ **Intercambio**	O	Nephropathy/ **Nefropatia**	O
Brain/ **Cerebro**	O	Protein/ **Proteina**	O	Hypoglycemia/ **Hiporglucemia**	O
Sugar/ **Azucar**	O	Injection/ **Inyeccion**	O	Endocrinologist/**Endocrinologo**	O
Fiber/ **Fibra**	O	Exercise/ **Ejercicio**	O	Ophthalmologist/ **Medico de los ojos**	O
Meal/ **Comida**	O	Diabetes	O	Triglyceride/ **Trigliceridos**	O
Meat/ **Carne**	O	Fluid/ **Suero**	O	Necrosis	O
Fruit/ **Fruta**	O	Portion/ **Porcion**	O	Cardiovascular disease/ **Enfermadad cardiovasculares**	O
Rice/ **Arroz**	O	Serving/ **Porcion**	O	Hyperglycemia/ **Hiperglucemia**	O
Bread/ **Pan**	O	Obesity/ **Obisidad**	O	Dialysis/ **Dialisis**	O
Heart/ **Corazon**	O	Dosage/ **Dosis**	O	Ketone/ **Cetona**	O
Blood/ **Sangre**	O	Calorie/ **Caloria**	O	Prescription/ **Receta**	O
Needle/ **Aguja**	O	Infection/ **Infeccion**	O	Amputation/ **Amputacion**	O
Hospital/ **Hospital**	O	Stroke/ **Derrame**	O	Pharmacist/ **Farmaceutico**	O
Vision/ **Vista**	O	Fasting/ **Ayuna**	O	Medication/ **Medicamento**	O
Snack/ **Merienda**	O	Glucose/ **Glucosa**	O	Lancet/ **Lanceta**	O
Strip/ **Tira**	O	Shaking/ **Temblar**	O	Pancreas	O
Insulin/ **Insulina**	O	Nutrition/ **Nutrición**	O	Glucometer/ **Glucometro**	O
Alcohol/ **Alcol**	O	Vegetable/ **Verdudas**	O	Cataract/ **Catarata**	O
Foot/ **Pie**	O	Emergency room/ **Sala de urgencias**	O	Carbohydrate/ **Carbohidrato**	O
Shock/ **Choque**	O	Swelling/ **Hinchazon**	O	Monitoring/ **Supervisión**	O
Diet/ **Dieta**	O	Sweating/ **Transpiracion**	O	Physical Activity/ **Actividad fisica**	O
Lab/ **Laboratorio**	O	Appointment/ **Cita**	O	Cholesterol/ **Colesterol**	O
Family history/ **Historia de familia**	O	Blood pressure/ **Presión arteria**	O	Hemoglobin A1C/ **Hemoglobina A1C**	O
Weight/ **Peso**	O	Refill/ **Rellenar**	O		
Nerve/ **Nervio**	O	Redness/ **Rojez**	O		
Cut/ **Corto**	O	Kidney/ **Riñón**	O		
Sore/ **Llaga**	O				

C-3: Personal Information

PERSONAL INFORMATION/***Información Personal***

1. What is your current employment status/***¿Cuál es su situación en el empleo?***
   - O Working full-time/***Trabajando a tiempo completo***
   - O Working part-time/***Trabajando medio tiempo***
   - O Unemployed/***Desempleados***
   - O Retired/***Jubilado***
   - O Disabled/***Discapacitado***
   - O Other/***Otro*** _____

2. Type of residence/***Tipo de residencia***
   - O Own/***Casa Propia***
   - O Living with relatives or friends/***Viven con familia o amigos***
   - O Renting/***Alquiler de casa***
   - O Public housing/***Hogar Publica***
   - O Other/***Otro*** _____

3. What is your household income?/***¿Cuál es su ingreso total de hogar?***
   - O Less than $10,000 for household per year/***Menos de $10,000 para el hogar/año***
   - O Between $10,001 and $15,000 for household per year/***Entre $10,001 y $15,000 para el hogar/año***
   - O Between $15,001 and $20,000 for household per year/***Entre $15,001 y $20,000 para el hogar/año***
   - O Between $20,001 and $40,000 for household per year/***Entre $20,001 y $40,000 para el hogar/año***
   - O Between $40,001 and $60,000 for household per year/***Entre $40,001 y $60,000 para el hogar/año***
   - O Over $60,001 for household per year/ ***Mas de $60,001 para el hogar/año***

4. What is your marital status?/ ***¿Cuál es su estado civil?***
   - O Single/***Soltera***
   - O Married/***Casada***
   - O Widowed/***Viuda***
   - O Divorced/***Divorciada***
   - O Partnered/***Una Pareja***

5. In what year were you diagnosed with diabetes?/***¿En qué año fueron diagnosticados con diabetes***? _____

6. How many family members live in your household?/***Cuantas personas de su familia viven en el mismo hogar?*** _____

7. Have you participated in any diabetes group classes sponsored by CommUnityCare?/ ***¿Usted ha participado en las clases en grupo de diabetes ofrecidos por CommUnityCare?***

O Yes (Go to 7-1)/ ***Sí (Sigue a 7-1)*** O No

7-1. If yes, how many times did you attend?/ ***En caso afirmativo, ¿cuantas veces usted asistio?***

_____

8. Have you worked with a dietician at CommUnityCare to manage your diabetes?/ ***¿Se ha reunido con una dietista en la CommUnityCare para aprendera manejar su diabetes?***

O Yes (Go to 8-1)/ ***Sí (Sigue a 8-1)*** O No

8-1. If yes, how many times have you met with a dietician at CommUnityCare?/ ***En caso afirmativo, ¿cuantas veces usted reunido con una dietista en la CommUnityCare?***

_____

9. What type of insurance do you currently have?/***¿Qué tipo de seguro tiene?***

- O Medicaid or CHIP
- O Medicare
- O Private Insurance/***Seguro Privado*** (Blue Cross/Blue Shield, Humana, etc.)
- O Do not have insurance/***No tengo seguro***
- O Other/***Otro*** _____

10. In general, what language(s) do you read and speak?/ ***¿Por lo general, cual idioma(s) puedes leer y hablar?***

- O Only Spanish/ ***Sólo Español***
- O Spanish better than English/ ***Más Español qué Inglés***
- O Both equally/ ***Ambos igualmente***
- O English better than Spanish/ ***Más Inglés qué Español***
- O Only English/ ***Sólo Inglés***

11. What language(s) do you usually speak at home?/ ***¿Por lo general, qué idioma(s) habla en su casa?***

- O Only Spanish/ ***Sólo Español***
- O Spanish better than English/ ***Más Español qué Inglés***
- O Both equally/ ***Ambos igualmente***
- O English better than Spanish/ ***Más Inglés qué Español***
- O Only English/ ***Sólo Inglés***

12. In which language(s) do you usually think? ***¿Por lo general, en qué idioma(s) piensa?***

- O Only Spanish/ ***Sólo Español***
- O Spanish better than English/ ***Más Español qué Inglés***
- O Both equally/ ***Ambos igualmente***
- O English better than Spanish/ ***Más Inglés qué Español***
- O Only English/ ***Sólo Inglés***

13. In what language(s) do you speak with your friends?/ ***¿Por lo general, qué idioma(s) habla con sus amigos?***

- O Only Spanish/ ***Sólo Español***
- O Spanish better than English/ ***Más Español qué Inglés***
- O Both equally/ ***Ambos igualmente***
- O English better than Spanish/ ***Más Inglés qué Español***
- O Only English/ ***Sólo Inglés***

14. What is the highest level of education that you completed?/ ***¿ Cuál es el nivel de educación más alto que ha completado?***

- O Did not graduate high school/ ***No me gradué de la secundaria***
- O Graduated high school/GED/ ***Gradué de la secundaria /GED***
- O Attended some college/ ***He asistido a colegio parcial***
- O Graduated college/ ***Me Gradué de la universidad***
- O Graduate Masters or PhD/ ***Posgrado Maestría o Doctorado***
- O Other (please specify)/ **Otra *(especifique)*** _____

C-4: Diabetes Self-Care Activities

DIABETES SELF CARE

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7days, please think back to the last 7 days that you were not sick./ ***Las preguntas que siguen son sobre sus actividades higiénicos para controlar su diabetes durante los últimos 7 días. Si estabas enfermo durante los últimos 7 días, por favor recuerda a los últimos 7 días que no estabas enfermo***

Diet/Dieta

How many of the last SEVEN DAYS have you followed a healthy eating plan?
¿Cuantos de los últimos SIETE DÍAS le siguió un plan de comida saludable?

O O O O O O O O
0 1 2 3 4 5 6 7

On average, over the past month, how many DAYS PER WEEK have you followed a healthy eating plan?
¿En el último mes, ¿cuántos DIAS DE LA SEMANA ha seguido un plan de comida saludable?

O O O O O O O O
0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?
¿Cuántos de los últimos SIETE DIAS comió cinco o más porciones de frutas y verduras?

O O O O O O O O
0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?
¿Cuántos de los últimos SIETE DIAS comió alimentos ricos en grasas como carne roja o productos lácteos?

O O O O O O O O
0 1 2 3 4 5 6 7

Exercise/ *Ejercicio*

On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).
¿En cuántos de los últimos SIETE DÍAS participó 30 minutos o mas de actividad física? (Minutos totales de actividad continua, incluso caminar)

O O O O O O O O
0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?
¿Cuántos de los últimos SIETE DIAS participó en un ejercicio específico (por ejemplo, nadar, caminar, andar en bicicleta) aparte de que haces en casa o como parte de su trabajo?

O O O O O O O O
0 1 2 3 4 5 6 7

Blood Sugar Testing/ *Prueba de azúcar en la sangre*
On how many of the last SEVEN DAYS did you test your blood sugar?
¿Cuántos de los últimos SIETE DIAS ha comprobado su azúcar en la sangre?

O O O O O O O O
0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?
¿Cuántos días en los últimos SIETE DIAS ha comprobado su azúcar en la sangre con la frecuencia recomendado de su médico?

O O O O O O O O
0 1 2 3 4 5 6 7

Foot Care/ *Cuidado del pie*

On how many of the last SEVEN DAYS did you check your feet?
¿Cuántos días de los últimos SIETE DIAS ha comprobado sus pies?

O O O O O O O O
0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you inspect the inside of your shoes?
¿Cuántos de los últimos SIETE DIAS ha comprobado el interior de sus zapatos?

O O O O O O O O
0 1 2 3 4 5 6 7

C-5: Diabetes Knowledge

DIABETES KNOWLEDGE

The following questions pertain to information about diabetes. For each question, please choose only one answer that you feel is correct./ ***Las siguientes preguntas se refieren a la información sobre la diabetes. Para cada pregunta, por favor, elija sólo una respuesta que es correcta***.

1. What is the best diet for a person with diabetes?
   ¿Cuál es la mejor dieta para una persona con diabetes?

   - O A diet which consists mainly of American foods/
     Una dieta que consiste principalmente de alimentos Americanos
   - O A diet that is good for the average person/
     Una dieta que es buena para la persona promedio
   - O A diet which has more carbohydrates than a common diet/
     Una dieta que tiene más carbohidratos que una dieta común
   - O A diet which has more protein than a common diet/
     Una dieta que tiene más proteína que una dieta común
   - O I don't know/ ***No se***

2. Which of the following is rich in carbohydrates?/ ***¿Cuál de las siguientes es rica en carbohidrato?***

   - O Roasted fish/ ***Pescado asado***
   - O Cheese/***Queso***
   - O Roasted potato/ ***Papa asada***
   - O Peanut butter/ ***mantequilla de maní***
   - O Don't know/ ***No se***

3. Which of the following is rich in fat?/ ***¿Cuál de las siguientes es alta en grasa?***

   - O Low fat milk/ ***Leche baja en grasa***
   - O Orange juice/ ***Jugo de naranja***
   - O Corn/***Maiz***
   - O Honey/***Miel***
   - O Don't know/ ***No se***

4. You can eat as much as you like of which of the following foods/ ***Puede comer todo lo que quiera de cuál de los siguientes alimentos:***

   - O Foods that are not sweet/ ***Alimentos que no son dulces***
   - O Diet foods/ ***Alimentos dietas***
   - O Foods marked "no sugar"/ ***Alimentos marcado "sin azucar"***
   - O Foods that are 20 calories or less per serving and have no limitations per serving/ ***Alimentos que son 20 calorías o menos/porción y sin limitaciones por porción***
   - O Don't know/ ***No se***

5. A hemoglobin A1c test indicates a patient's blood sugar control since/ ***Una prueba de A1c indica el control de azúcar en la sangre de un paciente desde:***

- O Yesterday/ ***Ayer***
- O Last week/ ***La semana pasada***
- O Last 2-4months/***2-4 meses***
- O Last 6 months/***4-6 meses pasados***
- O Don't know/ ***No se***

6. What is the most correct method of checking blood sugar?/ ***¿Cuál es el método más correcto de comprobar el azúcar en la sangre?***

- O Urine test/ ***Prueba de orina***
- O Blood test/ ***Prueba de sangre***
- O Urine test and blood test/ ***Prueba de sangre y orina***
- O Don't know/ ***No se***

7. What effect does fruit juice without sugar have upon one's blood sugar level?/ ***¿Qué efecto tiene el jugo de fruta sin azúcar con el azúcar en la sangre?***

- O It decreases blood sugar/ ***Azúcar en la sangre se reduce***
- O It increases blood sugar/ ***Azúcar en la sangre levanta***
- O It has no effect/ ***No tiene ningún efecto***
- O Don't know/ ***No se***

8. What is an ineffective way to quickly raise blood sugar?/ ***¿Qué es una manera mala para levantar rápidamente el azúcar en la sangre?***

- O Eat 3 pieces of candy/ ***Comer 3 pedazos de dulces***
- O Drink half a cup of orange juice/ ***Beber media taza de jugo de naranja***
- O Drink one cup of diet soda/ ***Beber una taza de soda dieta***
- O Drink one cup of fat-free milk/ ***Beber una taza de leche sin grasa***
- O Don't know/ ***No se***

9. What effect does exercise have on a person who is within a normal range of blood sugar?/***¿Qué efecto tiene ejercicio para una persona que está de un rango normal de azúcar en la sangre?***

- O It decreases the blood sugar/ ***Azúcar en la sangre se reduce***
- O It increases the blood sugar/ ***Azúcar en la sangre levanta***
- O It has no effect/ ***No tiene ningún efecto***
- O Don't know/ ***No se***

10. What happens to your blood sugar if you have a cold or wound, along with an infection?/***¿Qué pasa a su azúcar en la sangre si usted tiene un resfriado o una herida, con una infección?***

- O It decreases/ ***Azúcar en la sangre se reduce***
- O It increases/ ***Azúcar en la sangre levanta***
- O It has no effect/ ***No tiene ningún efecto***
- O Don't know/ ***No se***

11. Which of the following is the best method of taking care of your feet?/***¿Cuál de las siguientes es la mejor manera de cuidar de tus pies?***

- O Check feet and clean them everyday/ ***Revise pies y limpiarlos todos los días***
- O Massage feet with alcohol everyday/ ***Masaje de pies con alcohol todos los días***
- O Soak feet for an hour everyday/ ***Remoje los pies por una hora todos los días***
- O Wear shoes that are a large size/ ***Use zapatos que son de gran tamaño***
- O Don't know/ ***No se***

12. If you eat food with less fat:/***Si comes alimentos con menos grasa:***

- O It decreases the risk of neurological disease/

  Reduce el riesgo de enfermedad neurología
- O It decreases the risk of kidney disease/

  Reduce el riesgo de enfermedad renal
- O It decreases the risk of heart disease/

  Reduce el riesgo de enfermedad cardíaca
- O It decreases the risk of eye disease/

  Reduce el riesgo de enfermedad de los ojos
- O Don't know/ ***No se***

13. For what disease can numbness or tingling in the hands and legs be symptoms for?/ ***Entumecimiento u hormigueo en las manos y piernas son síntomas de cual enfermedad?***

- O Kidney disease/ ***Enfermedad renal***
- O Neurological disease/ ***Enfermedad de neurología***
- O Eye disease/ ***Enfermedad de los ojos***
- O Liver disease/ ***Enfermedad del hígado***
- O Don't know/ ***No se***

14. Which of the following possible complications is usually not associated with diabetes? ***¿Cuál de las siguientes complicaciones normalmente no están asociada con diabetes?***

- O Changes in vision/ ***Cambios en la visión***
- O Changes in the kidney/ ***Cambios en el riñón***
- O Changes in neurology/ ***Cambios neurología***
- O Changes in the lungs/ ***Cambios en los Pulmones***
- O Don't know/ ***No se***

********** Answer the following questions only if you take insulin injections. **********
*********Contesta las siguientes preguntas sólo si usted toma las inyecciones de insulin********

15. Which of the following is a symptom of ketoacidosis?/ ***El siguiente es un síntoma de cetoacidosis?***

- O Trembling/ ***Temblando***
- O Sweating/ ***Transpiración***
- O Vomiting/ ***Vómito***
- O Hypoglycemia/ ***Hipoglucemia***
- O Don't know/ ***No se***

16. Which of the following cautions should a diabetes patient follow when he or she catches a cold?/ ***Cuál de las siguientes precauciones debe un paciente de diabetes seguir cuando él o ella tiene un resfriado?***

- O Take less insulin/ ***Tomar menos insulin***
- O Drink less water/ ***Tomar menos agua***
- O Eat more protein/ ***Comer más proteínas***
- O More frequently check blood sugar and ketone levels/

  Compruebe azúcar en la sangre y niveles cetones con más frecuencia
- O Don't know/ ***No se***

17. If you take intermittent insulin, how long does it take for the insulin to be reactive?/ ***Si usted toma insulina intermitente, cuánto tiempo tarda la insulina para ser reactivo?***

- O 1-3 hours/***1-3 horas***
- O 6-12 hours/***6-12 horas***
- O 12-15 hours/***12-15 horas***
- O 20 hours/***20 horas***
- O Don't know/ ***No se***

18. You suddenly remember that you missed your insulin injection before lunch or after breakfast, you should:/***De repente se acuerda que se le olvido darse la inyección de insulina antes del almuerzo o después del desayuno, usted debe:***

- O Stop eating lunch in order to decrease your blood sugar/

  Dejar de comer el almuerzo para reduce el azúcar en la sangre
- O Immediately take your morning dosage of insulin/

  Inmediatamente tomar su dosis de insulina para la manana
- O Immediately give yourself an insulin injection with twice the normal dosage/

  Inmediatamente tomar una inyección de insulina doble la dosis normal
- O Decide whether or not to take your insulin injection after checking your blood sugar/

  Decidir si o no a tomar su insulina después de comprobar su azúcar en la sangre
- O Don't know/ ***No se***

********** Answer the following questions only if you take insulin injections. **********
********Contesta las siguientes preguntas sólo si usted toma las inyecciones de insulin********

19. If you start feeling hypoglycemic due to an insulin injection, you should:/***se siente hipoglicémico a causa de-a una inyección de insulina, usted debe:***

- O Exercise/ ***Hacer ejercicio***
- O Lie down and rest/ ***Acostar y relajar***
- O Drink juice/ ***Beber jugo***
- O Take insulin injection/ ***Tome la inyección de insulina***
- O Don't know/ ***No se***

20. Hypoglycemia is caused by:/***La hipoglucemia es causada por:***

- O Too much insulin/ ***Demasiada insulin***
- O Too little insulin/ ***Muy poca insulina***
- O Too much food/ ***Demasiada comida***
- O Too little exercise/ ***Muy poco ejercicio***
- O Don't know/ ***No se***

21. If you take an insulin injection while having missed breakfast, your blood sugar:/
Si se tomo una inyección de insulina sin desayuno, su azúcar en la sangre:

- O may increase/ ***Puede levantar***
- O may decrease/ ***Puede bajar***
- O may not change/ ***No puede cambiar***
- O Don't know/ ***No se***

22. Hyperglycemia is caused by:/***La hipoglucemia es causada por:***

- O Too little insulin/ ***Muy poca insulina***
- O Too little food/ ***Muy poca comida***
- O Too little snacks/***Muy poco bocadillos***
- O Too much ketones in urine/ ***Demasiado cetonas en orina***
- O Don't know/ ***No se***

23. What can cause hypoglycemia for insulin-taking patients?/ ***Que puede causar la hipoglucemia para pacientes que toman la insulina?***

- O Strenuous exercise/ ***Ejercicio vigoroso***
- O Infection/ ***Infección***
- O Overeating/ ***Comer en exceso***
- O Skipping insulin injections/ ***Saltar inyecciones de insulina***
- O Don't know/ ***No se***

C-6: Diabetes Self-Efficacy

DIABETES CARE CONFIDENCE

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time./ ***Nos gustaría saber qué tan seguro estás haciendo actividades. Para cada una de las siguientes preguntas, por favor, elija el número que corresponde a la confianza que usted puede hacer las tareas regularmente en la actualidad.***

1. How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?/ ***¿Qué tan seguro que piensas que puedes comer cada 4 a 5 horas cada día, incluyendo el desayuno todos los días?***

not at all confident/ ***absoluto no seguro***	O	O	O	O	O	O	O	O	O	O	totally confident/ ***totalmente confidente***
	1	2	3	4	5	6	7	8	9	10	

2. How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?/ ***¿Qué tan seguro piensa que usted puede seguir su dieta cuando tienes que preparar o compartir alimentos con otras personas que no tienen diabetes?***

not at all confident/ ***absoluto no seguro***	O	O	O	O	O	O	O	O	O	O	totally confident/ ***totalmente confidente***
	1	2	3	4	5	6	7	8	9	10	

3. How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)?/ ***¿Qué tan seguro piensa que puede elegir los alimentos saludables cuando tiene hambre (por ejemplo, bocadillos)?***

not at all confident/ ***absoluto no seguro***	O	O	O	O	O	O	O	O	O	O	totally confident/ ***totalmente confidente***
	1	2	3	4	5	6	7	8	9	10	

4. How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?/ ***¿Qué tan seguro piensa que puede hacer ejercicios por 15 a 30 minutos, cuatro o cinco veces la semana?***

not at all confident/ ***absoluto no seguro***	O	O	O	O	O	O	O	O	O	O	totally confident/ ***totalmente confidente***
	1	2	3	4	5	6	7	8	9	10	

5. How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?/ ***¿Qué tan seguro piensa que puede hacer algo para evitar su azúcar en la sangre bajando cuando usted hace ejercicio?***

not at all confident/ ***absoluto no seguro***	O	O	O	O	O	O	O	O	O	O	totally confident/ ***totalmente confidente***
	1	2	3	4	5	6	7	8	9	10	

6. How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?/ ***¿Qué tan seguro piensa que sabe que hacer cuando su azúcar en la sangre es más alta o más baja?***

not at all confident/ ***absoluto no seguro***	O	O	O	O	O	O	O	O	O	O	totally confident/ ***totalmente confidente***
	1	2	3	4	5	6	7	8	9	10	

7. How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?/***¿Qué tan seguro piensa que puede determinar cuando los cambios en su enfermedad requierir usted visitar al médico?***

not at all confident/ ***absoluto no seguro***	O	O	O	O	O	O	O	O	O	O	totally confident/ ***totalmente confidente***
	1	2	3	4	5	6	7	8	9	10	

8. How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?/ ***¿Qué tan seguro piensas que puedes controlar su diabetes para que no interfiera con las cosas que quieres hacer?***

not at all confident/ ***absoluto no seguro***	O	O	O	O	O	O	O	O	O	O	totally confident/ ***totalmente confidente***
	1	2	3	4	5	6	7	8	9	10	

C-7: Health Information-Seeking Behaviors

HEALTH INFORMATION

Please mark how much you agree or disagree with the following statements/ ***Por favor, marque su grado de acuerdo o desacuerdo con las siguientes afirmaciones:***

1. I don't have time to bother learning a lot of health information/ ***No tengo el tiempo para molestarme en aprender mucha información de salud.***

Strongly Disagree/ ***Fuertemente Desacuerdo***	Disagree/ ***Desacuerdo***	Neutral/ ***Ser Nutral***	Agree/ ***Acuerdo***	Strongly Agree/ ***Fuertememnte Acuerdo***
O	O	O	O	O

2. I make a point to read/watch stories about health/***Hago un punto para leer/mirar artículos sobre la salud***.

Strongly Disagree/ ***Fuertemente Desacuerdo***	Disagree/ ***Desacuerdo***	Neutral/ ***Ser Nutral***	Agree/ ***Acuerdo***	Strongly Agree/ ***Fuertememnte Acuerdo***
O	O	O	O	O

3. I don't pay attention to health information unless it's about a problem I have/***No presto atención a la información de salud a menos que sea sobre un problema que tengo***.

Strongly Disagree/ ***Fuertemente Desacuerdo***	Disagree/ ***Desacuerdo***	Neutral/ ***Ser Nutral***	Agree/ ***Acuerdo***	Strongly Agree/ ***Fuertememnte Acuerdo***
O	O	O	O	O

4. When sick, I try to get information about my disease/ ***Cuando enfermo, tratar de obtener información sobre mi enfermedad***.

Strongly Disagree/ ***Fuertemente Desacuerdo***	Disagree/ ***Desacuerdo***	Neutral/ ***Ser Nutral***	Agree/ ***Acuerdo***	Strongly Agree/ ***Fuertememnte Acuerdo***
O	O	O	O	O

5. I like to get health information from a variety of sources/***Me gusta conseguir la información de salud de una variedad de fuentes***.

Strongly Disagree/ ***Fuertemente Desacuerdo***	Disagree/ ***Desacuerdo***	Neutral/ ***Ser Nutral***	Agree/ ***Acuerdo***	Strongly Agree/ ***Fuertememnte Acuerdo***
O	O	O	O	O

6. When I take medicine, I try to get as much information about benefits and side effects/ ***Cuando tomo medicina, tratar de obtener tanto información sobre beneficios y efectos secundarios***.

Strongly Disagree/ ***Fuertemente Desacuerdo***	Disagree/ ***Desacuerdo***	Neutral/ ***Ser Nutral***	Agree/ ***Acuerdo***	Strongly Agree/ ***Fuertememnte Acuerdo***
O	O	O	O	O

7. Before making a decision about my health, I find out everything I can about this issue/***Antes de tomar una decisión acerca de mi salud, conseguir todo lo que puedo sobre de este tema***.

Strongly Disagree/ ***Fuertemente Desacuerdo***	Disagree/ ***Desacuerdo***	Neutral/ ***Ser Nutral***	Agree/ ***Acuerdo***	Strongly Agree/ ***Fuertememnte Acuerdo***
O	O	O	O	O

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